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Rhode Island Medical Journal

January 1984
Volume 67, Number 1

**DISPLAY
SHELVES**

The Doctor John E. Donley
Rehabilitation Center
in Providence
—See page 21



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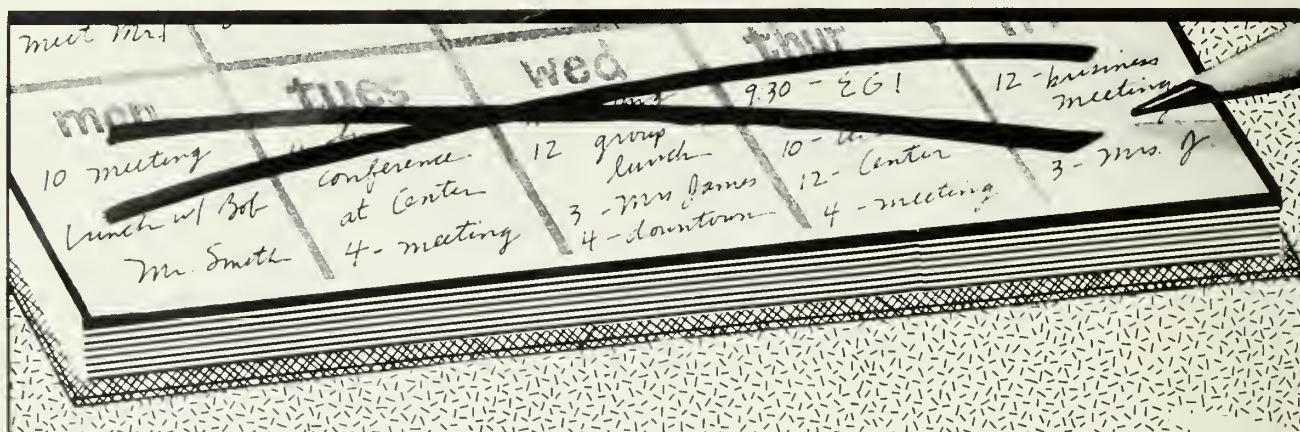
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Newsletter

RHODE ISLAND MEDICAL SOCIETY
January 1984

Charles P. Shoemaker, Jr., MD, President
Wendy J. Smith, Editor

FRANCIS A. COUNTWAY
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BOSTON, MA

FEB 22 1984

DISCUSSIONS WITH RI BAR ON INTERPROFESSIONAL CODE CONTINUE

It was reported at the December meeting of the RIMS Council that discussions are in progress with representatives of the Rhode Island Bar Association on a proposed revision of the 1976 interprofessional code between physicians and attorneys.

One of the more difficult issues faced by the liaison committee, according to its current chairman, Dr Paul T. Welch, centers around the release of medical records and the appropriate reimbursement for professional services. Many trial lawyers contend that physicians refuse to respond to their requests for medical information and in some cases may "hold the record hostage" in return for payment. Physicians, however, frequently must respond to such requests years after the treatment has been provided for patients who may never have paid their bills.

The confusion over the issue is further compounded by the fact that there is no universally acceptable definition of what material actually constitutes the "medical record." In other actions at its December 13 meeting, the Council:

- received a report on recommendations from the Commission on the Office of the State Medical Examiner. It has proposed that the Office should retain its current professional autonomy, but that responsibility for its fiscal, legal, and administrative activities should be transferred to the Department of Health. The Society has long been on record as supporting this position. Under the current system, the Department of Health must finance any deficits incurred by the Office from its limited discretionary funds.
- referred to a special committee a request from the Kent County Medical Society that the Society investigate the "fairness" of procedures utilized by the Board of Medical Review.
- noted that a record number of 750 subscribers enrolled in Blue Cross & Blue Shield programs sponsored by the Society for the current premium year.
- received an informational report on Medical Bureau, Inc which ceased operations in early November.
- agreed that the RIMS president should be seated as an additional "alternate delegate" in the AMA House of Delegates as permitted by AMA policy.
- received an informational report on the December 1983 meeting of the AMA Section Council on Hospital Medical Staffs which attracted more than 500 participants. The section, established last June to address the concerns of hospital-affiliated physicians, has stimulated considerable interest.
- noted that Congress narrowly defeated a bill in December which would have required physicians to accept assignment of Medicare benefits as

COUNCIL MEETING (continued)

"payment in full." The issue is expected to surface again shortly after Congress reconvenes this month.

- congratulated RIMS President Dr Charles P. Shoemaker, Jr. on the successful November 30 Symposium on Legal, Economic, and Social Issues (see below).
- adopted a policy statement on representation of the Rhode Island Medical Society to the General Assembly and other governmental bodies.
- noted the continuing discussions with representatives of New England Bell Telephone on the feasibility of a 911 emergency number system in Rhode Island. The state is one of the few jurisdictions in the country which does not have a single-number emergency system.

The Council also adopted a policy statement on the so-called Carcieri Commission. The Committee is expected to seek the reintroduction of legislation, narrowly defeated in 1983, which would impose a total dollar limitation on all hospital capital and acquisition projects, based on a loosely-defined concept of "affordability." The Council expressed the view that any position taken by the Society should emphasize that such arbitrary restrictions may well limit patient access to necessary medical services and hinder the development of future technological innovations.

* * *

TOWN/GOWN RELATIONSHIP AND OTHER DIFFICULT ISSUES ADDRESSED AT RIMS CONFERENCE

Although more than 20 percent of the private practicing physicians in Rhode Island serve on the voluntary faculty of the Brown University Program in Medicine, the town/gown schism will increase unless "many of the problems and proposed solutions filter through to the doctor on the street." This was one of the opinions expressed at a symposium on the legal, social, and economic aspects of medical practice held November 30 at the Rhode Island Medical Society.

More than 40 Rhode Island physicians, identified by their colleagues as having an interest in socio-economic issues, attended the meeting. According to RIMS President Dr Charles P. Shoemaker, Jr., one of the purposes of the meeting was to solicit "fresh approaches to old problems" from physicians who have not been active in the Society. It was modeled after similar programs sponsored by the American College of Surgeons and other national organizations.

Dealing with the Brown program, the symposium participants attributed many of the tensions between the academic and practice communities to increasing economic pressures. These include a heightened competition for "the limited health care dollar," the direct costs and indirect expenditures resulting from the Brown program, and the impact of training some 250 medical students and 400 residents in the state.

It was noted that many of the voluntary faculty and other physicians in community hospitals perceive a climate of "mistrust and lack of communication." While no definitive solutions were proposed, the Society's leadership was encouraged to pursue a more active liaison relationship with the academic community at Brown.

Other workshop sessions at the conference dealt with such diverse issues as a "physician glut," the malpractice crisis, the impact of closed medical staffs,

costs of medical care, and third-party reimbursement issues. As a result of these discussions, it was noted that:

- While some subspecialists may still be needed in limited areas of the state, an oversupply in most specialties exists in Rhode Island. This has stimulated pressures toward larger group practices, the hiring of more full-time salaried physicians, and "turf battles" between physicians and allied health providers. Concern also was expressed that, for some specialists, a smaller number of patients per physician may result in a deterioration of the physician's skills.
- The impact of closed hospital medical staffs and the limitation of privileges may well become an economic reality for many newly-trained physicians. A workshop assigned to this problem recommended that the manpower needs of each hospital be based on the anticipated patient volume and service requirements. Moreover, the criteria for staff appointments should be clearly stated with the final decision made by a committee and subject to legal review.
- Many proposals to remedy insurance and reimbursement inequities would be impractical to implement and politically unfeasible. Concern also was expressed about proposed legislation which would require mandatory assignment of Medicare benefits, freeze Medicare reimbursement for physicians, and extend the new diagnosis-related group (DRG) based system to physician services.
- Physicians must participate in business coalitions to control medical care costs if these efforts are to succeed.
- While the availability of malpractice insurance no longer presents as crucial a problem for most physicians as it did during the mid-1970s, several trends suggest that the malpractice crisis is getting worse.

Among these are the continued high costs of premiums, the growing number of claims filed, and the larger awards granted to claimants. A panel assigned to the problem emphasized that a clear distinction must be made between malpractice and an unexpected event resulting from good medical care. It also was noted that the Society plans to sponsor an aggressive legislative program in 1984, and that a future issue of the Rhode Island Medical Journal will focus on the problem.

* * *

AMA POLICY ON CONFIDENTIALITY CLARIFIED

The confidentiality of the physician/patient relationship must be maintained to the "greatest degree possible," according to a report approved last month by the AMA House of Delegates.

Emphasizing that patients must feel free to talk openly with their physicians, the report prohibits the release of confidential information, "unless required to do so by law," without the specific consent of the patient.

This obligation, the report notes, is subject to certain exceptions which are "legally and ethically justified because of overriding social considerations." If a patient threatens to harm another person, the physician should take "reasonable precautions to protect the intended victim," including notification of law enforcement authorities. Moreover, communicable diseases and gunshot and knife wounds should be reported as required by law or "local practices."

GREENHOUSE COMPACT MAY AFFECT RHODE ISLAND PHYSICIANS

The Rhode Island Strategic Development Commission (the so-called Murray Commission) has proposed the establishment of two new entities which may ultimately affect the practices of Rhode Island physicians.

The recommendations were included as part of a complex proposal, known as the Greenhouse Compact, to revitalize the state's economy.

A proposed new research institute, to be called the Universal Health Information Service, represents an effort to capitalize on the estimated \$30-50 million spent on the laboratory and clinical testing necessary for each new drug and medical device. The new institute, which would be based on "existing institutional capabilities at Brown University, the University of Rhode Island, and in the state's hospitals," would provide a "full range of services" to facilitate the development of new pharmaceuticals and medical devices.

Another new organization, the Institute for Geriatric Enterprise, also would be built on existing institutional bases. It would be responsible, according to an "executive summary" published by the Commission, for providing "research and development consultations" to groups and businesses interested in supplying goods and services to the elderly. The Commission report notes that the elderly represent a "rapidly-growing, previously untapped market" with demonstrable needs for "health care, improved institutional care, specially trained personnel, and medical and consumer products."

Legislation resulting from the Greenhouse recommendations is expected to be the subject of intense debate during the 1984 session of the Rhode Island General Assembly. The Society's Public Laws Committee has been charged with monitoring those bills which may apply to physicians.

* * *

PERIPATETICS

Society members in the news include:

- Joseph Amaral, MD, Providence, was one of six residents and fellows at Rhode Island Hospital to receive a Haffenreffer Fellowship for 1983-1984. The fellowship was established by the Haffenreffer family of Rhode Island in 1946 to encourage original research. Dr. Amaral is a first-year fellow in the Department of Surgery, Surgical Research.
- Recently designated chairman of the Cancer Clinical Investigation Review Committee of the National Cancer Institute was Louis Leone, MD, Providence. Dr. Leone has served on the committee, which reviews grant applications for cancer cooperative group programs, since 1980.
- Georges Peters, MD, Providence, recently was elected to membership in the American Pediatric Society, Inc. The organization honors those persons who, by their contributions to pediatrics, have aided in its advancement.
- Recipient of the Distinguished Alumni Award of the Chicago Medical School was Arvin S. Glickman, MD, Providence, for his work in the field of radiation cancer therapy.

* * *

NOTE: The "Practice Management Question of the Month" will return to this space in the February 1984 NEWSLETTER.

Continuing Medical Education

SEMI-ANNUAL CALENDAR OF CONTINUING MEDICAL EDUCATION EVENTS

NOTE: Lectures and courses are listed by the date, sponsor, topic, speaker, and telephone number for additional information. Please call the contact number for specific information about the program.

JANUARY

- 3 St. Joseph Hosp., "The Significance of Lymphocytes Subsets in Clinical Medicine," Salvatore Allegra, MD, 456-3000
- 9 General Hosp. RIMC, "Unusual Clinical and Pathological Aspects of Alzheimer's Disease," S. Pogacar, MD, 456-3493
- 9 Fogarty Memorial Hosp., "Hypertension," Wilson S. Colucci, MD, 769-2200 ext 238
- 10 Roger Williams General Hosp., "Calcium Channel Blockers in Cardiovascular Disease," Joseph Alpert, MD, 456-2033
- 12 RIH, "Advances in Psoriasis Therapy" and "Arachidonic Acid & Leukotrienes in the Pathophysiology & Treatment of Common Skin Diseases," John J. Vorhees, MD, 277-5507
- 13 Kent County Memorial Hosp., "CHF," Wilson S. Colucci, MD, 737-7000
- 16 Woonsocket Hospital, "LVD and Sudden Cardiac Death," Joseph Alpert, MD, 767-3211
- 16 RIH, "CT and Ultrasound of the Kidney: New Observations," and "Gynecologic Ultrasonography," Arthur T. Rosenfield, MD, 277-5138
- 19 RIH, "Inflammatory Bowel Disease in the Pediatric Patient," 277-5721
- 19 General Hosp. RIMC, "Clinical Neuropathological Conference," Pasquale F. Finelli, MD; S. Pogacar, MD, 464-3493
- 20 Kent County Memorial Hosp., "Peptic Ulcer," Saul Feldman, MD, 737-7000
- 20 Roger Williams General Hosp., "LHRH: The Ups and Downs of Puberty," William Crowley, Jr., MD, 456-2350
- 23 General Hosp. RIMC, "Health Economics and the Elderly," Jaana-Marja Muurineu, PhD, 464-3493
- 26 General Hosp. RIMC, "Epidemiology of Work-Related Disease," Stanley Aronson, MD, 464-3493
- 27 Kent County Memorial Hosp., "New Pathogens and New Pneumonias," Deiter Gump, MD, 737-7000

FEBRUARY

- 6 General Hosp. RIMC, "Drug Interaction Survey Among Elderly Hospital Population," Norma J. Owens, PhD, 464-3493
- 7 St. Joseph Hosp., "Herpes Update," David Lowe, MD, 456-3005/945-6610
- 9 General Hosp. RIMC, "Epidemiology of Venereal Disease," Stanley Aronson, MD, 464-3493
- 9 RIH, "Psychocutaneous Dermatologic Disorders," and "Bacterial, Fungal & Viral Infections in Immunosuppressed Patients," Sigfrid A. Muller, MD, 277-5507
- 10 Kent County Memorial Hosp., "Allergy," John M. O'Loughlin, MD, 737-7000
- 14 General Hosp. RIMC, "Psychogeriatric Case Presentation," Jorge Scott, MD; Jack Mioni, MD, 464-3493
- 15 Miriam Hospital, "The Simeone Oration on History and Medicine," Guido Majno, MD, 456-2350
- 16 General Hosp. RIMC, "Clinical Pathological Conference," 464-3493
- 17 Roger Williams General Hosp., "Prenatal Cardiac Diagnosis," Charles S. Leinman, MD, 456-2350
- 23 General Hospital RIMC, "Epidemiology and Biology of Hepatitis A&B," Stanley Aronson, MD, 464-3493
- 27 RIH, "Digital Subtraction Angiography: Current Applications," Donald F. Denny, MD, 277-5183
- 29 Memorial Hospital, "Kenney Day and Luncheon," Program to be announced, 722-6000 ext 2142

MARCH

- 2 Kent County Memorial Hosp., "Calcium Channel Blockers," Kenneth Salz-sieder, MD, 737-7000
- 8 RIH, "Prognostic Factors in Clinical Stage I Melanoma," and "Precursor Lesions in Melanoma," Arthur J. Sober, MD, 277-5507
- 8 General Hosp. RIMC, "Epidemiology of Motor Vehicle Mortality in the State of Rhode Island," Stanley Aronson, MD, 464-3493
- 12 Fogarty Memorial Hosp., "Agoraphobia," Paul Alexander, MD, 769-2200
- 13 General Hosp. RIMC, "Psychogeriatric Case Presentation," W. Japlit, MD; Hugo Taussig, MD, 464-3493
- 16 Roger Williams General Hosp., "Shunt and Shunt Infections," John Shillito, Jr., MD, 456-2350
- 19 General Hosp. RIMC, "Alzheimer's Disease and Its Mimics," Richard L. Wagner, MD, 464-3493

MARCH

- 19 Woonsocket Hosp., "An Update on Ace Inhibition on Hypertension and Heart Failure," Mark Creager, MD, 767-3211, ext. 2311
- 19 RIH, "Generalized Orthopedic Diseases of Childhood," M.B. Ozonoff, MD, 277-5183
- 21 RIH, "Psychiatry and Dissent: The Soviet Experience & Its Implications," Walter Reich, MD, 277-5488
- 22 Miriam Hosp., "The Kiven Oration," Guido Majno, MD, 274-3700, ext 4810
- 22 General Hosp. RIMC, "Epidemiology of Measles," Stanley Aronson, MD, 464-3493
- 23 Kent County Memorial Hospital, "Hypertension Management in the 1980s," Mark Wineberg, MD, 737-7000
- 28 General Hosp. RIMC, "Clinical Neuropathological Conference," Thomas D. Sabin, MD; S. Pogacar, MD, 464-3493

APRIL

- 2 General Hospital RIMC, "Pulmonary Thromboembolism in the Chronically Ill," Jean K. Ashba, MD, 464-3493
- 3 St. Joseph Hosp., "Clinical Application of Laser in Head & Neck Surgery," Anthony Barone, MD, 456-3005/942-6610
- 5 General Hosp. RIMC, "Epidemiology of Nervous System Infections," Stanley Aronson, MD, 464-3493
- 9 Fogarty Memorial Hosp., "Diabetes and New Human Insulins," Edward O. Reiter, MD, 769-2200 ext 238
- 10 General Hosp. RIMC, "Psychogeriatric Case Presentation," E. Dimen, MD; Ando Suvari, MD, 464-3493
- 12 RIH, "Argon Laser Therapy of Port Wine Stains & Other Vascular Lesions," and "Control of Keratinocyte Proliferation: An In Vitro Perspective," Barbara A. Gilchrest, MD, 277-5507
- 13 Roger Williams General Hosp., "Management of Pharyngitis in the Era of Decline of Rheumatic Fever," Milton Markowitz, MD, 456-2350
- 19 General Hosp. RIMC, "Clinical Pathological Conference," 464-3493
- 24 RIH, "CT of Sciatica," Victor M. Haughton, MD, 277-5183
- 25 RIH, "Joint Meeting of RI Radiologic Society & Department of Neurosurgery," and "CT of the Intervetebral Disc," 277-5183

MAY

- 1 St. Joseph Hosp., "Senile Dementia & Alzheimer's Disease," John Rowe, MD, 456-3005/942-6610
- 10 RIH, "Topic to be announced," Roy Steele Rogers, III, MD, 277-5507
- 14 Fogarty Memorial Hosp., "Gay Bowel Syndrome," J. Kheradi, MD, 769-2200

MAY

- 15 General Hosp. RIMC, "Psychogeriatric Case Presentation," R. Mate, MD; Jack Mioni, MD, 464-3493
- 16 Miriam Hosp., "The Lichtman Oration," Thomas Almy, MD, 274-3700, ext. 4810
- 17 RIH, "Skin Cancer," 277-5721
- 21 RIH, "Radiology of the Spine," and "Disorders Affecting the Hands," Harold G. Jacobson, MD, 277-5183
- 24 General Hosp. RIMC, "Clinical Neuropathological Conference," Thomas F. Morgan, MD, 464-3493
- 25 Roger Williams General Hosp., "Virus Infections of the CNS," Samuel L. Katz, MD, 456-2350

JUNE

- 5 St. Joseph Hosp., "Differential Diagnosis of Upper Abdominal Pain," Erminio Cardi, MD, 456-3005/942-6610
- 12 General Hosp. RIMC, "Psychogeriatric Case Presentation," A. Andronic, MD; Hugo Taussig, MD, 464-3493
- 14 RIH, "Cutaneous T-Cell Lymphoma," Loren E. Gorlitz, MD, 277-5507
- 21 General Hosp. RIMC, "Clinical Pathological Conference," 464-3493

CONTINUING ACTIVITIES

Brown Univ. Program in Medicine & Roger Williams General Hosp.: Every Friday, "Rheumatology Grand Rounds," call 456-2069 for information.

Brown Univ. Program in Medicine & Butler Hospital: Third Thursday of the month, September through May, "Academic Grand Rounds in Psychiatry;" third Monday, "Neuroscience Seminars," VA Medical Center; first Thursday, "Chairman's Case Conference," call Butler Hospital at 456-3700 for additional information.

Pawtucket Memorial Hospital: Every Monday and Tuesday, "Medicine/Family Medicine Core Curriculum;" every Tuesday, "Cardiology Conference;" every Wednesday, "Hematology/Oncology Conference," "Medical Grand Rounds," "Pathology Conference," first and third Wednesday, "Tumor Board Conference;" second and fourth Wednesday, "Pulmonary Case Review;" every Thursday, "OB/GYN Conference," Family Practice Grand Rounds," "Orthopedic Conference," and "Surgical Grand Rounds," call 722-6000 ext. 2142 for specific information about topics and speakers.

Roger Williams General Hospital: Fourth Thursday, Department of Pathology and Laboratory Medicine, "Clinicopathological Conference," call 456-2166 for additional information.

Institute of Mental Health: Every Friday, "Community Ward Seminar," call 464-2416 for additional information.



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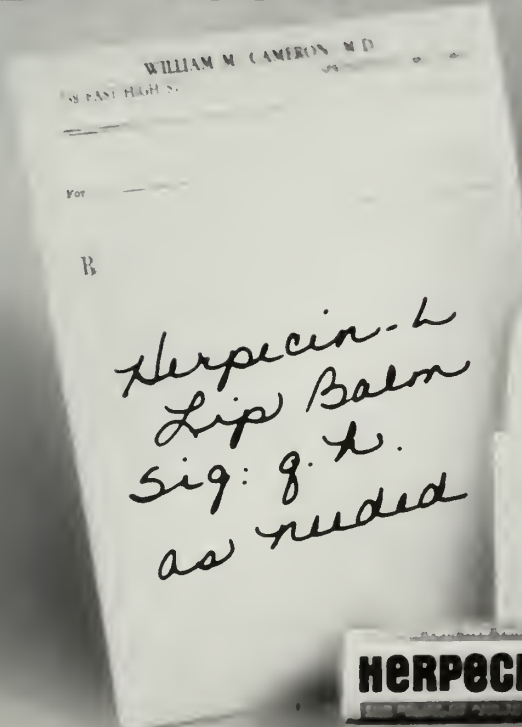
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_____ 015 Insulin
_____ 038 Iron Supplements
_____ 033 Levodopa/Carbidopa and
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_____ 021 Lithium
_____ 014 Methylodopa
_____ 030 Metronidazole
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The Doctor John E. Donley Rehabilitation Center on Blackstone Boulevard in Providence. For more on the Center's program, see page 21.

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EDITORIAL

A New Look at the Fiscal Impact of the Malpractice Crisis

The total bill for the malpractice premiums of the nation's physicians, their skilled employees, and hospitals will reach an estimated \$3.5 billion for the year 1983. This figure includes a projected premium cost of \$1.645 billion to \$1.75 billion for physician coverage alone. Hospitals throughout the country will pay an equivalent amount for their liability insurance, and physicians will cover an additional \$2-3 million in premiums to protect their skilled paramedical employees against legal action.

Not included in the tabulation is the estimated \$15.1 billion price tag for "defensive medicine" and other indirect costs associated with professional liability. This has been defined by one study commission as "the alteration of modes of medical practice, induced by the threat of liability, to forestall the possibility of lawsuits by patients and to provide a good legal defense if such lawsuits are initiated." According to one AMA survey, more than 40 per cent of physicians in 1981 ordered additional diagnostic tests and 27 per cent performed therapeutic procedures solely to protect themselves against potential claims. It has been estimated that such procedures accounted for five per cent of the total 1982 health care expenditure of \$322 billion.

These figures, reported last month at the AMA Interim Meeting, represent the first attempt to measure the total financial impact of the malpractice crisis on the nation's health care bill. Previous estimates have addressed only such out-of-pocket expenditures as premium payments and legal expenses. Even these costs remain difficult to calculate as there is no national clearinghouse of information on the total premiums paid by physicians and hospitals for professional liability coverage. For the first time, the AMA committee responsible for the project also estimated the dollar value of the indirect costs related to the professional liability situation. Among these were the impact of the early retirement of physicians as the result of litigation, the loss of professional income for time spent on depositions and in trial proceedings, and the productivity costs of physician dysfunction once a claim has been filed.

Discussing trends and factors, the AMA Committee on Professional Liability concluded that no segment of litigation has enjoyed a more rapid growth during the past 15 years than claims related to medical care. It has resulted in a new legal specialty with its own training programs, post-graduate courses, professional journals, and the other trappings of specialization. The AMA committee also reported on the increasing number of physicians who serve as expert witnesses. An estimated 3,000 physicians derive a substantial portion of their professional income from such activities, prompting calls for the formal training of physicians as expert witnesses in medical school.

Recent trends suggest a worsening of the professional liability situation in Rhode Island. It has been estimated that malpractice claims currently are pending against one of every three physicians in the state. According to the Medical Malpractice Joint Underwriting Association (JUA), 1,748 physicians paid a total of \$6,945,774 in premiums in 1982, the last year for which figures are available. Thirteen hospitals paid a total of \$1,804,684 in premiums to the JUA last year.

Because of the direct costs of the professional liability crisis to its members and the indirect impact on the state's economy, the Rhode Island Medical Society has focused considerable attention on the issue. Many of the legislative reforms obtained in 1975 and 1976, including arbitration panels, restrictions on the statute of limitations, and so forth, have been judged unconstitutional by the courts. Under the leadership of President-Elect Doctor Paul J. M. Healey, the Committee on Professional Liability has outlined a program to seek legislative relief on such difficult problems as collateral source payments and awards for pain and suffering. Malpractice was the focus of intense discussion at a recent symposium on social economic, and legislative problems sponsored by the Society. A future issue of this *Journal* will be devoted to an analysis of the malpractice crisis from the perspectives of the legislative, judicial, and legal systems.

Wendy J. Smith

PRESIDENT'S PAGE



Notes of a Convention Watcher — Part II*

The American Medical Association House of Delegates held its interim session December 4-7 in Los Angeles. The AMA House meets twice a year, generally in late June and early December. The Rhode Island Medical Society again was well represented by Doctors John J. Cunningham, Delegate, and Herbert F. Hager, Alternate. Members of the "unofficial" delegation included Doctors Paul J. M. Healey, Peter L. Mathieu, Jr., Norman A. Baxter, and myself.

One of the most controversial issues to surface dealt with third-party reimbursement for physician services. On the eve of the meeting, a bill which would have required physicians to accept assignment of Medicare benefits was defeated by four votes in the US House of Representatives, primarily as the result of intense AMA lobbying. It is likely that the mandatory assignment issue will emerge again shortly after Congress reconvenes, and another tough battle to maintain the status quo is expected.

A related issue, indemnification versus "usual, customary, or reasonable" (UCR), also attracted considerable attention at the meeting. An AMA committee had recommended last June that the organization consider withdrawing its support of the UCR approach to physician reimbursement and instead endorse indemnification as the preferred method of payment. RIMS members who attended an open meeting on the issue last November raised serious doubt about whether indemnification would work in Rhode Island. Essentially, it would permit physicians to bill patients for the difference between the insurance payment and their professional charges. Many RIMS members voiced concerns that patient access to necessary medical services would be restricted solely for financial reasons. The indemnification issue also was hotly debated on the floor of the AMA House. The delegates reaffirmed their position that, while fees should be deter-



Charles P. Shoemaker, Jr., MD

mined by physicians, we must remain sensitive to the financial resources of our patients. As the debate continued, it became evident that AMA members are involved in widely-varying types of contractual relationships, and it appears doubtful that we will see a widespread move to indemnification.

Two other controversial issues before the AMA House were the insanity defense and proposed revisions by the Joint Commission on the Accreditation of Hospitals (JCAH) regarding hospital medical staffs. The AMA's opposition to the plea "not guilty by reason of insanity" attracted national television coverage and drew the opposition of the American Psychiatric Association and the American Bar Association. At the very least, the AMA's position should stimulate extensive discussion. It may well result in some legislative initiatives to eliminate the insanity defense.

Dealing with the proposed JCAH revisions, the AMA House adopted the following statement: "That it be the policy of the AMA that hospital admitting privileges be granted in accordance with state law and in accordance with the criteria

* Notes of a Convention Watcher — Part I, RI Med J 66(8):305-306, 1983.

for medical care standards established by the individual medical staff." This statement culminates a three-year long struggle between representatives of the American College of Surgeons, other specialty organizations, and the AMA leadership. The College sought language which would reaffirm the existing JCAH position that all hospital patient care should be under the direct responsibility of fully-licensed physicians or osteopaths. Because this restriction has been the target of antitrust litigation, the AMA maintained that it should be eliminated from the revised JCAH standards. The compromise language recognizes that, because podiatrists and other limited-license practitioners have hospital admitting privileges in 21 states, the JCAH standards cannot be used to exclude them from patient care activities. The medical staff, however, retains the sole responsibility for establishing patient care standards and the degree of supervision necessary for allied health personnel. While the new language satisfies concerns about adequate supervision of non-physicians, it does not address the problem that supervising physicians may as a result suffer from increased exposure to professional liability.

Other hospital-related issues discussed at the AMA House meeting were diagnosis-related group (DRG) based reimbursement, legal services for medical staffs, and closed medical staffs. The House directed the AMA to investigate problems which apparently have resulted from DRGs. Some hospitals reportedly are planning not to renew clinical privileges for physicians who prove to be "unprofitable" under the DRG system. It is a further concern that hospitals may well attempt to control physician reimbursement if these payments are also linked to a DRG-type mechanism.

The House also reaffirmed the concept that medical staffs should retain their own legal counsel, independent of any legal services provided by the hospital administration. The problem of closed medical staffs generated several resolutions from the medical student and resident business sections, as these two groups are especially worried about the availability of hospital privileges for newly-trained physicians.

Because of the diversity and occasional opposing interests of individual AMA members, it is really quite remarkable that the AMA delegates can reach a consensus on many thorny problems. Some of these deliberations may seem remote from our daily professional activities, but they form the basis for such lobbying efforts as the

AMA's opposition to mandatory assignment. While some 83 per cent of all Medicare claims in Rhode Island last year were paid on an assignment basis, the option to reject it as "payment in full" keeps the pressure on Congress to maintain Medicare fees at a reasonable level. If the AMA position on Medicare continues to prevail, those of us who treat Medicare patients will be indebted to the AMA many times over the cost of our dues.

Physician Manpower in Rhode Island

The recent decision by the Brown University Program in Medicine to create 40 new full-time positions sent shock waves through the entire medical community. Concerns and anxieties surfaced immediately from two groups specially affected by the plans. One group, the many newly-trained physicians, are already struggling to survive in the face of the "doctor glut." The other group consists of third-party payers, who estimate that the cost of funding salaries, benefits, and support staff for each new position will reach at least \$300,000. This will result in an additional expense of some \$12 million for the state's strained economy.

Is this a problem? If so, should the Rhode Island Medical Society address it? The second question is more easily answered. In response to a proposal several years ago to the Statewide Health Coordinating Council (SHCC) that the Rhode Island Department of Health require the geographic and specialty distribution of physicians within the state, the Society volunteered to assume responsibility for defining manpower needs. The SHCC proposal was never approved. While the Society did initiate a manpower study, this activity sputtered and remains to be completed. In response to recent events, however, it has become increasingly evident that it must be finished. The recent acquisition of an in-house computer should help considerably. As for defining the problem, while the planned Brown expansion and perceived "doctor glut" would strongly suggest the presence of "too many physicians," such an oversupply must be carefully documented if our conclusions are to be credible.

We have been assured that Brown University and the affiliated hospitals have evaluated their own manpower requirements thoroughly. Among the issues studied by the University were the existing lack of some specialties and subspecialties in the state, the need for educational improvements, and the income needs of the University and hospitals. These certainly are legiti-

mate concerns. However, community-based physicians, the non-affiliated hospitals, and the public may well have other considerations. Moreover, because of the impact of the expansion on the costs of medical care, third-party payers certainly must participate in these decisions.

Another issue which compounds the "manpower problem" is the fact that we function in a voluntary environment. The AMA has long advocated free choice and the continuation of a marketplace economy, and, until recently, plans by hospitals to expand their facilities remained unfettered by external restraints. Since these decisions, however, affect the state's economy as a whole, it seems reasonable to conclude that some form of regulation will emerge. This may be in the form of a regulatory body or a voluntary board whose decisions would be advisory and non-binding.

We strongly believe that the latter approach is preferable, especially for decisions affecting physician manpower. The key players in such activities obviously are the medical schools, hospitals, practicing physicians, and Blue Cross & Blue Shield, and all must participate on an equal basis. Without cooperation, the pressures for mandatory controls will continue to mount, to the

detriment of the interests of everyone. If the supply of physicians continues to expand, we can predict further government intrusion into the practice of medicine.

As the first step in the process, we have asked Doctors Pierre Galletti and David Greer of the Brown program to convene a meeting of the RIMS/Brown Liaison Committee. One of their agenda items will be consideration of the establishment of a voluntary advisory committee which might include two physicians appointed by the Society, two physicians appointed by the Brown University Program in Medicine, and representatives from the Rhode Island Department of Health, Blue Cross & Blue Shield of Rhode Island, and the Hospital Association of Rhode Island. The committee, whose opinions would be advisory and nonbinding, could be charged with evaluating manpower needs, the size of the Brown University Program in Medicine, and the number of residency positions, and making appropriate recommendations.

It must be emphasized that these recommendations would be advisory and would not be binding on any of the participants. Rather, the process of reaching them would expand the participation base, so that the impact of such expansions on all of us may be appropriately evaluated.

The Doctor John E. Donley Rehabilitation Center: A Community Resource

Rhode Island Physicians Should Utilize These Facilities for the Benefit of Their Patients

Henry M. Litchman, MD
Stanley D. Simon, MD

The Doctor John E. Donley Rehabilitation Center, formerly the Rhode Island Curative Center, was established in 1943 by the General Assembly of Rhode Island to provide "all possible modern curative treatment and methods" to injured workers covered by the Worker's Compensation Law. It became the first state-operated rehabilitation facility in the country. In 1961, the center was renamed to honor the memory of its first medical director, who had long advocated the establishment of a statewide treatment program. Among his many other professional accomplishments, Doctor Donley served as president of the Providence Medical Association and the Rhode Island Medical Society and as Editor of the *Rhode Island Medical Journal*.

The Center is financed through a special revenue fund. The principal source of income consists of annual mandatory contributions paid by all insurance companies which underwrite worker's compensation and employers' liability cover-

age in Rhode Island. Employers who self-insure against these risks also must contribute to the fund. Other Center revenue is derived from investment income and nominal treatment fees.

The Center, located at 249 Blackstone Avenue in Providence, recently completed a 1.7 million dollar construction and expansion program to offer optimal treatment and rehabilitation to the injured worker. The new construction consists of 50,000 square feet of additional building space, which includes a swimming pool designed for therapeutic purposes and improved facilities for physical and occupational therapy. The expanded quarters also will permit the Center to treat five times as many patients.

Relationship of the Center to Referring Physicians

The Worker's Compensation Law requires that all therapy at the Center be supervised by medical experts and provided only after consultation with the injured employee's own physician. A staff of 36 employees and eight consultants, functioning under an 11-member advisory board, perform physical therapy, psychotherapy, occupational therapy, and vocational rehabilitation counseling services.

Although funded by insurance companies and self-insured employers, the Center exists solely for the benefit and rehabilitation of the injured worker. If specific prescriptions are written by the referring physician, every attempt is made to follow these requests. When the treatment program is left to the judgment of the medical staff, a comprehensive protocol is outlined and implemented with periodic reports to the referring physician. Modifications in treatment programs are made upon request, and therapeutic regi-

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Stanley D. Simon, MD, is in the private practice of orthopedic surgery, Providence, Rhode Island; formerly Director, Orthopedic Surgery, The Miriam Hospital, he is Clinical Associate Professor of Orthopedics, Brown University Program in Medicine. Doctor Simon has served as Medical Director of the Donley Rehabilitation Center since 1976.

mens are frequently changed in response to the changing nature of the patient's condition. While supervising physicians at the Center are not exempt from testifying before the Worker's Compensation Commission, traditionally they have not participated in the hearing process since their role is limited to supervising and carrying out therapy. They should not be regarded as potential threats to referring physicians as they do not advocate either side during the adjudication process.

The involvement of the Center in the rehabilitation process begins with a referral by the treating physician. It must be accompanied by



documentation of the history and findings, as well as a prescription for the proposed therapy. During the patient's initial visit to the Center, a review of the diagnostic data and a physical examination are performed by the medical staff, the chief physical therapist, and the occupational therapist.

After a specific treatment program is outlined, the patient receives daily therapy with the most advanced equipment and techniques available in a comprehensive setting. The treatment may include physical therapy, occupational therapy, and such other supportive services as psychotherapy, vocational rehabilitation, and English les-

sons for foreign-born patients. With the growing recognition of the availability of these services, the number of patients treated at the Center has doubled between 1976 and 1982, at which time the program was functioning at nearly 90 per cent of the capacity then available. The ability of the Center to treat additional patients is expected to increase with the recent expansion.



Departments

The physiotherapy department comprises the most active part of the program. In addition to such standard facilities as a whirlpool, hydrocolator, and traction equipment, it also includes a Cybex® exercise table and a Universal Gym.® The swimming pool offers a new dimension to the program by providing the patient with an oppor-

tunity to exercise lower extremity fractures in a buoyant partial weight-bearing environment.

The occupational therapy department administers a majority of the programs designed to alleviate problems related to the upper extremities. It also operates such programs as woodworking and, in the near future, ceramics, which are carefully planned to enhance the patient's ability to return to work.

The vocational rehabilitation department is staffed by qualified counselors who serve as con-

a more comprehensive understanding of occupational hazards and the effectiveness of treatment modalities.

Experience

The Center focuses on the problems of patients who have been slow to recover from occupational injuries. The median length of time between occurrence of an accident and admission to the treatment program is 5.3 months. Approximately 20 per cent of the cases involve injuries that occurred more than one year prior to admission. Eighty per cent of the patients are male, and two-thirds of the referred patients report back injuries as their primary problem. More than half



sultants during therapy. In addition, some patients are referred to the Center only for this aspect of the program.

The volume of patients under treatment permits the Center a rare opportunity to develop and implement new dimensions to the rehabilitation process. At the present time, there is a continuing study of transcutaneous electrical stimulation for the alleviation of pain and expansion of exercise capacity, and further studies are under consideration. The computerization of treatment and history data from the Center should contribute to

of the patients are reported as "well" or "improved" at the time of discharge. The median duration of treatment is 10.5 weeks.

The approach of the Center to the chronic back patient is more comprehensive than most physicians are capable of providing in their offices. The well-motivated patient with minimal organic pathology, seen in the office setting shortly after the injury, usually recovers in two to three months with a simple therapeutic regimen. The patients referred to the Center, however, often present with more complicated problems. The



first group of these patients frequently are post-operative failures in which the presenting pathophysiology has become secondary to the intervention. A second group consists of those patients, both with and without organic pathology, for whom psychological factors may retard the rehabilitation process. A third group of patients, especially difficult to treat, includes those presenting with the so-called "pain syndrome." While they frequently are dependent on drugs for the alleviation of the unexplained pain, they reveal no significant clinical findings.

These types of patients require rehabilitation to overcome some of the problems secondary to their original injury. They often have a loss of tissue elasticity and muscle competence and exhibit a continuing cycle of pain, anxiety, tension, and inhibition, leading to additional pain and continuation of the cycle.

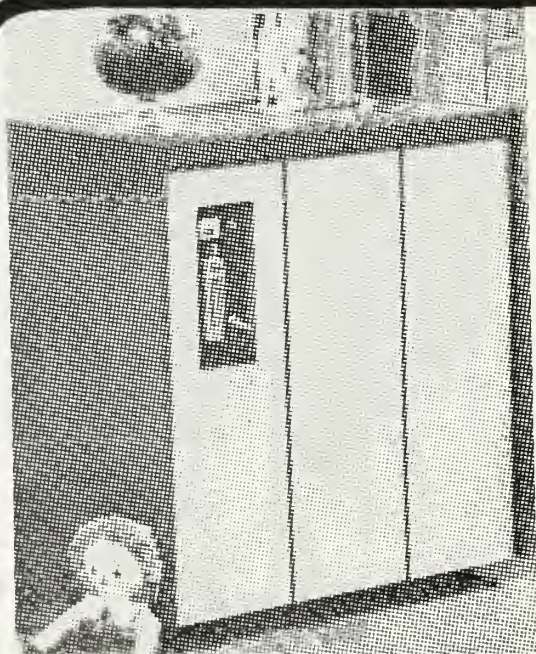
A multidisciplinary approach to evaluation and treatment provides the most effective therapy available for such patients. Experience has demonstrated the efficacy of pool therapy, combined with slow stretching exercises, in restoring lost tissue elasticity. While the hydraulic therapy pro-

vides a form of muscle heating and relaxation, the process of slow stretching prevents hyperactive responses and takes advantage of the viscoelastic nature of the muscle.

Gentle active exercise is essential to the rehabilitative process. To reduce pain during the early phases of therapy, simultaneous transcutaneous electrical stimulation has been selectively utilized. Active exercise enhances joint motion and muscle strength. When this is well tolerated, the patient progresses to isometric techniques, followed by resistance exercises.

A general fitness program also is initiated, utilizing such devices as bicycle ergometers and treadmills, followed by an occupational therapy program. As the objective is to restore the injured worker to productive activity, vocational counselors also work with patients during the rehabilitation process.

It is hoped that Rhode Island physicians will recognize the opportunities available through this community resource and will utilize these facilities more fully for the benefit of their patients.



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Traffic Fatalities in Rhode Island: Part I — Descriptive Epidemiology

*Traffic Fatalities Account for 17.6 Per Cent of All
Years of Life Lost Before Age 65*

Kemi Nakabayashi, AB
Sarah C. Aronson, AB
Michael Siegel
William Q. Sturner, MD
Stanley M. Aronson, MD

During the past decade, 1.4 per cent of the deaths in Rhode Island were caused by traffic accidents. Because these deaths preferentially involve younger people, traffic fatalities presently constitute the greatest single etiologic factor in the potential years of life lost.

This epidemiologic inquiry surveys all traffic mortalities, as determined by the Office of the Medical Examiner, within the state of Rhode Island for the years 1977 through 1982.* To the extent that a very small number of these deaths involve non-residents passing through or temporarily residing within the state, the resultant mortality rates are not a totally accurate reflection of the Rhode Islanders who die as a result of traffic accidents. A total of 766 deaths will be analyzed in terms of customary population attributes. When appropriate, the resultant distributions will be compared with the population characteristics of Rhode Island and the United States.

The present paper represents the first of a series analyzing these traffic fatalities. The intent of this first paper is to provide a demographic framework for subsequent efforts, and more extensive discussions will be found in later papers.

The following meaning of the term *fatal traffic accident* has been observed in this study. The event resulting in the death of one or more per-

sons must involve one or more motorized vehicles, and their loads, in motion on a roadway which is open to the public and customarily used for motor vehicle travel. The fatality must take place within 30 days of the accident.¹

Definitions of other terms used in this and subsequent papers are as follows:

Motor vehicles (MV): Licensed, engine-driven vehicles with four or more wheels, including automobiles, trucks, and buses.

Motorcycles (MC): Licensed, engine-driven vehicles with two wheels, including mopeds.

Pedestrians: All non-occupants involved in motor vehicle fatalities, including persons on foot or bicycle.

Traffic fatalities (TF): Deaths involving drivers (motor vehicles or motorcycles), passengers (motor vehicles or motorcycles), or pedestrians.

Source of Data and Methods

The records of the Office of the Medical Examiner, State of Rhode Island, were reviewed for the calendar years 1977-1982, and all traffic fatalities fulfilling the above description were extracted. The following information was then gathered on each fatality: sex, race, age at death, fatality-status (ie, motor vehicle driver, motor vehicle passenger, motorcycle driver, motorcycle passenger,

This and subsequent papers in this series represent undergraduate honors studies undertaken at Brown University, Providence, Rhode Island. At the present time, Kemi Nakabayashi is a medical student at Case-Western Reserve University; Sarah C. Aronson is a medical student at Dartmouth Medical School; and

Michael Siegel continues his undergraduate studies at Brown University. William Q. Sturner, MD, is Chief Medical Examiner, State of Rhode Island, and Professor of Pathology, Brown University Program in Medicine. Stanley M. Aronson, MD, is University Professor of Medical Science, Brown University.

Table 1. Traffic Fatalities in Rhode Island: Victim Status and Year

Status of Victim	1977	1978	1979	1980	1981	1982	Total
Male:							
Motor vehicle driver	41	38	47	49	42	29	246
Motor vehicle passenger	18	15	20	14	8	12	87
Motorcycle driver	17	15	12	15	17	20	96
Motorcycle passenger	0	0	1	1	1	2	5
Pedestrian	24	22	14	20	22	18	120
Unknown	0	1	0	0	0	0	1
Total traffic fatalities (TF)	100	91	94	99	90	81	555
Total accidental deaths	198	162	166	191	160	142	1,019
Percentage of accidental deaths due to TF	50.5	56.2	56.6	51.8	56.3	57	54.5
Female:							
Motor vehicle driver	13	12	12	12	16	8	73
Motor vehicle passenger	16	9	19	11	10	12	77
Motorcycle driver	0	0	0	1	0	0	1
Motorcycle passenger	1	3	1	1	0	1	7
Pedestrian	8	10	10	7	7	11	53
Unknown	0	0	0	0	0	0	0
Total traffic fatalities (TF)	38	34	42	32	33	32	211
Total accidental deaths	76	62	84	74	65	61	422
Percentage of accidental deaths due to TF	50	54.8	50	43.2	50.8	52.5	50.0
Ratio: Male TF/Female TF	2.6	2.7	2.2	3.1	2.7	2.5	2.6
RI Traffic Fatalities	138	125	136	131	123	113	653*
US Traffic Fatalities	47,878	50,331	51,093	51,077	49,268	N/A	249,661†
Ratio: RI TF/US TF $\times 10^{-3}$	2.88	2.48	2.66	2.56	2.50	—	2.62

* Only 1977-1981 included in total.

† Source: 1981 Statistical Abstract of the United States.⁷

pedestrian, or unknown), marital status, time of accident (hour, day of week, and date), date of death, occupation, toxicologic studies (blood alcohol concentration, blood CO concentration, semi-quantitative tests for narcotics, stimulants, sedatives, and other potentially psychoactive drugs), nature of accident, and nature of sustained trauma. The information on each of these 766 fatalities was appropriately coded and then entered into the computer at Brown University, Providence, Rhode Island. The tabular distributions noted below were then generated.

Results

Table 1 summarizes the traffic fatalities in terms of three discrete variables: sex, status of victim, and year of death. During this six-year period,

the average annual number of traffic deaths in Rhode Island was 128. While the annual number has been somewhat lower than this average during the last two years of this survey, the decrease was not statistically significant. During this same six-year interval, males constituted approximately 72 per cent of these traffic fatalities. No secular trends are apparent in the ratio of male to female victims or in the relative percentage contributions of motor vehicle driver, passenger, or pedestrian traffic fatalities.

Traffic fatalities are included in the larger category, Accidents and Adverse Effects (International Classification of Disease codes E800-E949),² and account for approximately 55 per cent of male and 50 per cent of female accidental deaths. No substantive changes in these percentages are apparent during this six-year span.

Table 1 also includes data on traffic fatalities in the United States for the years 1977 through 1981. The Rhode Island and national data are fairly congruent without any significant varia-

* During the calendar years 1977 through 1982, there were 793 traffic fatalities in Rhode Island. Complete information was available on 766 of these fatalities, which form the basis for this report. All of the information was tabulated and coded numerically without names or addresses to preserve the privacy of those involved.

tions.

Table 2 provides data concerning the sex and traffic status of the victim. For the entire population of 766 persons, the male to female ratio is 2.6. This ratio, however, is not maintained when the data is further analyzed according to the status of the victim. For example, there is a higher frequency of males among motor vehicle drivers (ratio — 3.4) and motorcycle drivers (ratio — 96); in contrast, there is an approximate sex parity among the motor vehicle passenger and motorcycle passenger victims. The sex ratio of pedestrians (2.3) is slightly lower than the overall traffic fatality ratio of 2.6. These sex-related differences are more evident when the data are analyzed in terms of active (ie, driver) or passive (ie, passenger or pedestrian) status. Some 61.7 per cent of all male victims were in active status, while only 35.1 per cent of females were active. Motorcycle fatalities (combining driver and passenger deaths) are dominantly male with a sex ratio of 12.6.

Table 3 introduces the variable of age in its relation to the sex and status of the victims. The age distribution in each of the status categories is non-uniform. The greatest single cluster of traffic fatalities is concentrated in the 15-24 year old male driver category. Male drivers (motor vehicles and motorcycles) alone account for 342 of the 766 fatalities (44.6 per cent). The peak numbers of traffic deaths occur in the 15-24 age category for both passengers and drivers, regardless of sex. With pedestrians, however, there is a bimodal distribution with concentrations of cases noted below the age of 15 years and above the age of 65 years.

When the data in Table 3 are considered primarily by category of age, the following becomes apparent. Below the age of 14 years, most victims are in the essentially passive pedestrian status (70.5 per cent). Above the age of 15 years, most traffic fatalities involve drivers. The relative percentage of active status (ie, driver fatalities/total motor vehicle fatalities) diminishes after age 54 years. Between the ages of 15 and 34 years, 62.7 per cent of fatalities are drivers; between ages 35 and 54 years, 63.2 per cent; between ages 55 and 74 years, 47.4 per cent; and beyond 75 years, 29.8 per cent.

When these same data are further analyzed by sex, the active status percentage of male traffic victims maintains a high level (about 61 per cent) until the age of 65 years, after which it decreases substantially. In the case of female victims, the percentage of active status fatalities reaches a peak in the age category of 35 to 44 years and then diminishes, but less precipitously, than with the males.

Table 3 also provides age-related incidence rates according to the status of victim and sex, averaged over the six-year span of the study. The traffic fatality incidence rate equals the number of traffic fatalities in any particular sex and age category per year divided by the total number of persons at risk in the sex and age category during the same year. A somewhat different pattern now emerges. The traffic mortality rate per 100,000 population per year in males over the age of 85 years is now as great as in males 15-24 years of age because the denominator in the rate equation, the number of males who are 85 years of age or older, is so small. For similar reasons, the mortality rates

Table 2. Traffic Fatalities in Rhode Island: Sex and Status of Victims (1977-1982)

Status of Victim	Male		Female		Sex Ratio*
	Number	Per Cent	Number	Per Cent	
Motor vehicle driver	246	44.4	73	34.6	3.4
Motor vehicle passenger	87	15.7	77	36.5	1.1
Motorcycle driver	96	17.3	1	.5	96.0
Motorcycle passenger	5	.9	7	3.3	.7
Pedestrian	120	21.7	53	25.1	2.3
Total	554†	100	211	100	2.6
Active (driver)‡	342	61.7	74	35.1	4.6
Passive (passenger or pedestrian)§	212	38.3	137	64.9	1.5
Total motor vehicle	333	60.1	150	71.1	2.2
Total motorcycle	101	18.2	8	3.8	12.6

* Sex ratio — number of males number of females

† One male not included in tabulation because of unknown status

‡ Active — drivers of motor vehicles or motorcycles

§ Passive — passengers of motor vehicles or motorcycles and pedestrians

Table 3. Traffic Fatalities in Rhode Island: Victim Status, Age, and Age-Related Incidence

	Age In Years										Total
	0-4	5-14	15-24	25-34	35-44	45-54	55-64	65-74	75-84	85 +	
Number of males:											
Motor vehicle driver	0	2	100	54	24	27	14	12	9	4	246
Motor vehicle passenger	3	5	54	14	3	2	0	3	2	1	87
Motorcycle driver	0	2	56	32	3	2	1	0	0	0	96
Motorcycle passenger	0	0	4	1	0	0	0	0	0	0	5
Pedestrian	2	25	17	15	11	10	11	14	13	2	120
Unknown	0	0	0	0	1	0	0	0	0	0	1
Total	5	34	231	116	42	41	26	29	24	7	555
Annual incidence rate per 100,000 population — males:											
Motor vehicle driver	0	0.5	20.0	13.3	8.8	10.1	4.9	6.5	11.3	20.4	9.1
Motor vehicle passenger	1.9	1.3	10.8	3.4	1.1	0.7	0	1.6	2.5	5.1	3.2
Motorcycle driver	0	0.5	11.2	7.9	1.1	0.7	0.4	0	0	0	3.5
Motorcycle passenger	0	0	0.8	0.2	0	0	0	0	0	0	1.0
Pedestrian	1.3	6.5	3.4	3.7	4.0	3.7	3.9	7.6	16.4	10.2	4.4
Total	3.2	8.8	46.2	28.5	15.0	15.2	9.2	15.8	30.2	35.7	20.5
Number of females:											
Motor vehicle driver	0	0	22	20	11	6	6	4	4	0	73
Motor vehicle passenger	0	6	32	16	1	5	4	2	8	3	77
Motorcycle driver	0	0	0	0	1	0	0	0	0	0	1
Motorcycle passenger	0	0	6	1	0	0	0	0	0	0	7
Pedestrian	2	14	5	4	4	6	3	4	8	3	53
Total	2	20	65	41	17	17	13	10	20	6	211
Annual incidence rate per 100,000 population — females:											
Motor vehicle driver	0	0	4.3	4.8	3.8	2.0	1.8	1.5	2.6	0	2.4
Motor vehicle passenger	0	1.6	6.3	3.8	0.3	1.7	1.2	0.8	5.3	5.9	2.6
Motorcycle driver	0	0	0	0	0.3	0	0	0	0	0	<0.1
Motorcycle passenger	0	0	1.2	0.2	0	0	0	0	0	0	0.2
Pedestrian	1.3	3.8	1.0	1.0	1.4	2.0	0.9	1.5	5.3	5.9	1.8
Total	1.3	5.4	12.8	9.8	5.8	5.7	3.9	3.8	13.2	11.8	7.1

for pedestrian victims is substantially higher in the later decades of life for both males and females. The relative weights of driver, passenger, and pedestrian victims at various age-categories are the same as those noted in other states and countries.³⁻⁵

Table 4 compares the age-related frequencies of motor vehicle fatalities for Rhode Islanders with similarly constructed rates for the US population. Virtually no differences are seen in the age profiles of motor vehicle drivers. There are some differences in distribution when the age profile of passengers and pedestrians from Rhode Island are compared with the US fatalities. These state rates, however, are not stand-

ardized to the national sex and age distribution, nor are such factors as urban versus rural conditions considered.

Discussion

Traffic fatalities represent a tragic and unnecessary loss of lives. While they account for only 1.4 per cent of deaths in Rhode Island and approximately 2 per cent of deaths in the United States,¹ they nevertheless represent the largest single cause of death between the ages of 5 and 34 years. Of the 207 male deaths in this age bracket recorded in Rhode Island in 1981, 82 (39.6 per cent) were due to identified accidents, of which 51 (24.6 per cent) were traffic fatalities. Of the 91

Table 4. Traffic Fatalities in Rhode Island: Age Distribution in Percent of Rhode Island and National Traffic Fatality Populations

	Age in Years				Unknown	Total
	0-14	15-34	35-64	>65		
Motor vehicle driver						
RI	0.6	61.4	27.6	10.3	0	99.9
US	0.5	61.5	29.0	8.4	0.7	100.1
Motor vehicle passenger						
RI	8.5	70.7	9.1	11.6	0	99.9
US	13.0	58.0	17.6	10.4	1.0	100.0
Pedestrian						
RI	24.9	23.7	26.0	25.4	0	100.0
US	18.9	34.2	25.0	18.9	3.1	100.1

Source: Fatal Accident Reporting System 1981. National Highway Traffic Safety Administration, January 1983.

deaths in Rhode Island females between the ages of 5 and 34 in 1981, 31 (34.1 per cent) were the result of accidents. Some 23 of these (25.3 per cent) were caused by traffic fatalities.

The social burden of these avoidable deaths can be better appreciated by a statistic initiated by the Centers for Disease Control in 1982 which designates the potential years of life lost (ie, the estimated annual total of potential years lost before age 65 years) for each major cause of death in the United States.⁶ By this measurement, traffic fatalities account for 17.6 per cent of all of the years of life lost by those Americans who die before age 65 years.

Are there any significant differences, in terms of crude mortality rates, when Rhode Island is contrasted with the other five New England states? If comparisons are confined to traffic accident fatalities per 10⁶ population, without age standardization, then Rhode Island has the lowest traffic fatality rate of any of the New England states. The Rhode Island rate is 136.1/10⁶ person-years (ie, 136.1 traffic fatalities/1,000,000 population at risk/year) while the New England rate is 175.1/10⁶ person-years.

When traffic fatalities are compared to annual vehicle miles driven, a more accurate parameter of the risk, the difference between Rhode Island and the rest of New England diminishes. The Rhode Island rate is 2.4/10⁸ vehicle miles driven/year, while the New England rate is 2.8/10⁸. During this same interval, the motor vehicle fatality rate for the continental United States was 3/10⁸ vehicle miles driven/year.

Conclusions

The following major conclusions may be drawn from the accompanying tables:

There are no notable secular trends in Rhode Island traffic fatalities during the interval under consideration.

About one-half of those killed in traffic accidents are males less than 34 years old.

Motor vehicle driver deaths account for 41.6 per cent of all traffic fatalities while motorcycle driver deaths result in an additional 12.7 per cent. Passenger deaths amount to 23 per cent and pedestrian deaths, 22.6 per cent.

The males killed in traffic accidents are more commonly drivers, while the females killed are more often passengers or pedestrians. In both sexes, the active/passive status ratio diminishes beyond middle age.

While the number of traffic fatalities for individuals more than 75 years old is relatively small (4.6 per cent), the age-related mortality rates are in the same range as the 15-34 year old population because the elderly population at risk is even smaller.

The age distribution of the Rhode Island passengers and pedestrians involved in traffic fatalities is somewhat different than the general age distribution of victims in the United States, but these data have not been standardized by sex or age, nor have such variables as miles driven per licensed person per year or relative road conditions been considered.

Subsequent papers in this series will be devoted to: the hour of day, day of week, and month as predicting factors in traffic fatalities; the influence of such variables as marital status, occupation, blood alcohol concentration, and psychoactive drugs; epidemiological studies of motorcycle fatalities; and descriptive information concerning the 173 pedestrian deaths during the six-year period.

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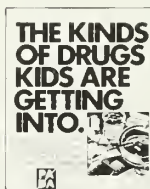
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Gastric Outlet Obstruction Produced By Gallstones in the Duodenal Wall

An Unusual Disorder Is Managed By Cholecystectomy and Gastrectomy

John L. Margolis, MD
Anthony V. Migliaccio, MD, FACS
Anthony J. Migliaccio, MD, FACS

Fistula formation between the extrahepatic biliary tree and the gastrointestinal tract is a well-known entity.¹⁻⁷ Although most of these fistulae are uncomplicated, obstruction of the intestinal lumen does occur. The point of obstruction is usually the terminal ileum. However, examples of gastric outlet obstruction as a result of intraduodenal calculi have been described.^{8, 9} We wish to report an unusual case of gastric outlet obstruction produced by intramural gallstones.

Case Report

A 77-year-old man was admitted to Rhode Island Hospital in February 1980 with a principal complaint of postprandial emesis. The symptoms began several months prior to admission when he began to vomit partially digested food approximately two hours after meals. Emesis occurred more frequently during the following weeks, but liquids were tolerated without difficulty. He denied the presence of abdominal pain, hematemesis, or melena, but did acknowledge a 30-pound (13.6 kg) weight loss. Studies performed on an outpatient basis included a barium enema revealing diverticulosis, a gallbladder series showing

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Fig 1. Upper gastrointestinal study showing gastric outlet obstruction

gallstones, and an upper gastrointestinal study indicating gastric outlet obstruction (Fig 1).

On admission to the hospital, the patient appeared younger than his age. He was afebrile. There was no icterus. Abdominal examination revealed no tenderness, distention, organomegaly, masses, or ascites. Stool guaiac was negative. Pertinent laboratory data included a white blood count of 5.7 without a left shift. Hemoglobin was 13.4 grams. Electrolytes were normal as was the alkaline phosphatase. Mild elevations of SGOT (51 IU/dL), LDH (447 IU/dL), and bilirubin (1.3 mg/dL) were noted.

After adequate preoperative intravenous fluid therapy and nasogastric suction, an operation was performed. A small, contracted gallbladder, containing many gallstones, was found densely adherent to the distal stomach and duodenum. After a cholecystectomy, a two-thirds distal gastrectomy with Billroth II anastomosis was performed to relieve the outlet obstruction. Upon opening the operative specimen, a cavity in the duodenal submucosa was found to contain multiple calculi (Figs 2-3). The senior surgeon (A.V.M.) felt that these intramural stones compressed the duodenal lumen sufficiently to cause obstruction of the gastric outlet.

The postoperative period was complicated by a bile leak, which closed spontaneously, and the patient was discharged without further complications. The final pathology report revealed chronic cholecystitis with ulceration, chronic gastritis with mucosal atrophy and small leiomyomata, and intramural calculi of the duodenal wall. No duodenal mucosal ulceration was detected.

Comments

The exact incidence of biliary enteric fistulization is uncertain,⁶ but it has been estimated that between three and five per cent of patients with cholelithiasis will eventually develop a communication between the extrahepatic biliary tree and the gastrointestinal tract.² Such fistulae occur between the gallbladder and the duodenum in 75 to 90 per cent of the reported cases.¹⁻⁷ Obstruction of the intestinal lumen secondary to fistulization has been reported in two to 34.5 per cent of patients with biliary enteric fistulae.⁴⁻⁶ While the terminal ileum is the most common site of obstruction,⁶ several examples of gastric outlet obstruction produced by intraduodenal gallstones have been described.^{8,9} This case presents another, if more unusual, case of gallstone obstruction of the gastric outlet. More importantly, it graphically illustrates the process of biliary enteric fistulization associated with chronic cholecystitis and cholelithiasis.

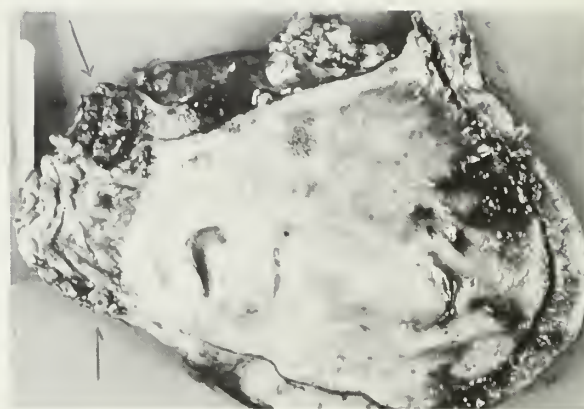


Fig 2. Gross operative specimen with gallstones in duodenal wall

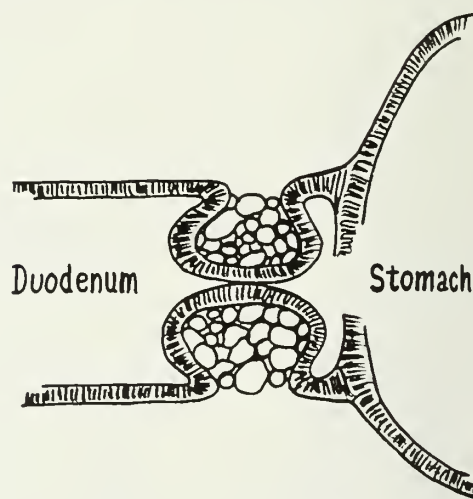


Fig 3. Artist's representation of intramural gallstones obstructing the duodenum

Summary

Gastric outlet obstruction was produced by gallstones which had migrated into, but not through, the duodenal wall. Successful relief was obtained by cholecystectomy, subtotal gastrectomy, and Billroth II gastrojejunostomy.

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Case Record: Rhode Island Hospital

Maurice M. Albala, MD
Tom J. Wachtel, MD
George F. Meissner, MD
Mark Fagan, MD, Editors

Presentation of Case

A 56-year-old white male bus driver was admitted to the hospital following sudden onset of chest pain.

Three years prior to this admission, the patient had been hospitalized for transient right upper extremity numbness and weakness. Cerebral arteriography and exercise treadmill tests were normal. The patient sought no further medical attention despite recurrent episodes of weakness and diaphoresis, which usually subsided spontaneously within 20 minutes and were not associated with chest pain, palpitations, or loss of consciousness.

There was no history of hypertension or diabetes. The patient was a former smoker. Family history was significant for hypertension, stroke, and myocardial infarction. The patient took no medications and denied any allergies.

On the day of admission, as he was about to begin work, the patient suddenly developed non-radiating substernal chest pressure associated with slight dyspnea and diaphoresis. After one hour of persistent chest discomfort, the patient was brought to the emergency room.

Physical examination revealed a middle-aged male complaining of mild chest pressure. Temperature 97°F (36.1°C) by mouth; blood pressure 150/90; pulse 60; and respiration rate 22. The head examination was normal except for marked arteriovenous nicking in both fundi. The neck was supple. There was no jugular venous distension or adenopathy. Carotid pulses were full with normal upstrokes. Lungs were clear. Cardiac examination revealed a regular rate and rhythm with normal first and second heart sounds, and no murmurs, rubs, or gallops. Abdomen and extremities were unremarkable. Neurological examination was normal except for loss of pain sensation in the right fourth and fifth fingers, which had developed three years earlier.

Initial laboratory studies revealed a creatinine of 1.4, but otherwise normal blood chemistries (blood urea nitrogen 17). The white blood count (WBC) was 12,400 with a normal differential. Hemoglobin (Hb) was 17.6 g per cent. Prothrombin activity was 98 per cent. Urinalysis showed a specific gravity of 1.030 with 1+ protein, 0-2 red blood cells (RBC), and 0-2 white blood cells (WBC). Room air arterial blood gas revealed pH 7.40; pO₂ 72 and pCO₂ 29 torr; and total CO₂ 18 mEq/L.

The chest x-ray film showed a prominent left ventricle, tortuous aorta, and clear lung fields. The electrocardiogram (EKG) showed normal sinus rhythm with normal conduction times. There was no ectopy. Q waves inferiorly suggested previous myocardial infarction. R waves were small in leads V₁ through V₃. T waves were flat in lead I and inverted in leads AVL, V₅ and V₆, consistent with anterolateral ischemia (Fig 1).

Sublingual nitroglycerin 1/150 grain (0.4 mg) and hydromorphone hydrochloride (1 mg intravenously) were administered for relief of chest pain, and intravenous lidocaine was infused prophylactically.

After admission to the hospital, two further episodes of chest pressure, without further EKG changes, responded to nitrates and morphine sulfate. Nitroglycerine paste was administered and increased to three inches every four hours.

Serial cardiac enzymes revealed SGOT values of 92, 70, and 44 IU/dL (normal 5-31); total LDH of 907, 650, and 475 IU/dL (with LDH 1 less than LDH 2) (normal 125-385); and total CPK of 226, 138, and 82 IU/dL with corresponding myocardial fractions (MB) of 19 and 13 (normal 0-40).

On the second hospital day, the patient complained of occasional pleuritic chest pain. Temperature 100.4°F (38°C), blood pressure 134/96, pulse 81, and respiration rate 16. Lungs were clear. Cardiac examination was remarkable

for a three-component rub. Chest x-ray findings were unchanged and an EKG now showed 1 mm ST elevations in leads I, II, AVL, and V₄-V₆. In addition, the previously inverted T waves in leads AVL, V₅, and V₆ had become upright (Fig 2). WBC was 16,000 with 75 per cent polymorphonuclear leukocytes, 1 per cent bands, 12 per cent lymphocytes, 11 per cent monocytes, and 1 per cent eosinophils. Hb was 15.0 g per cent. Westergren sedimentation rate was 25 mm/hour. Lidocaine was discontinued, and the patient received propranolol (10 mg every six hours), isosorbide dinitrate (40 mg every four hours), diazepam, and aspirin.

On the fourth day, one episode of midsternal chest pressure was relieved with a sublingual nitroglycerin tablet. A pericardial rub was still audible. EKG was unchanged, and cardiac enzymes were normal. On the fifth hospital day, syncope occurred after a bowel movement. Hypotension (systolic BP 50 mm Hg) and bradycardia (heart rate 40) resolved with Trendelenburg positioning and atropine (1 mg). On the sixth day, the patient was ambulatory and denied any chest discomfort. No rub was heard, and the lungs remained clear. EKG showed persistent ST elevations in leads I and II and telemetry recorded occasional aberrantly conducted premature auricular contractions (Fig 3). Later that day, the patient collapsed after returning from the bathroom. Cardiopulmonary resuscitation was initiated, the patient intubated, and a pacemaker positioned because of intractable sinus bradycardia. After unsuccessful attempts to convert ventricular tachycardia and fibrillation, the patient died.

Differential Diagnosis

Thomas Drew, MD*: This patient was a 56-year-old male with a history of "transient right upper extremity numbness and weakness" several years prior to his current problem. It remained unexplained at that time after a work-up which included cerebral angiography. The possibility of an underlying or associated cardiac illness obviously was raised, and an exercise treadmill test was normal. He had recurrent episodes of weakness and diaphoresis. It is not stated in the protocol whether the weakness was focal, or whether it occurred with increasing frequency before his present admission. Certainly, transient arrhythmias can be associated with weakness and

diaphoresis despite the lack of palpitations or loss of consciousness. Angina could also evoke episodes of weakness and diaphoresis, although there was little in the history to suggest it at that time. Recurrent transient ischemic attacks are possible despite the negative cerebral arteriography. Finally, these symptoms are nonspecific enough and could have been related to anxiety.

The present illness started with chest pressure and associated dyspnea and diaphoresis. On initial examination his elevated blood pressure (150/90) could have been stress related. The finding of hypertension was corroborated by significant arteriovenous nicking noticed on funduscopic examination. The mildly elevated respiratory rate could be attributed to anxiety. The rest of the examination was noteworthy for the paucity of findings. In particular, the lack of extrasystoles or murmurs and the presence of both heart sounds virtually excludes acute severe aortic regurgitation. The lack of focal neurological findings, other than a history of sensory loss, argue against ongoing focal embolic phenomenon. The laboratory data suggest abnormal renal function with a creatinine of 1.4, and urinalysis reveals 1+ protein which perhaps is attributable to his chronic hypertension. The Hb is elevated, suggesting underlying lung disease, although there is nothing in the history to suggest this other than his being a former smoker. The specific gravity of 1.030 indicates a degree of hemoconcentration which may explain the elevated hemoglobin concentration. Blood gases reveal some hyperventilation with a PCO₂ of 29 and an increased arterioalveolar gradient with a PO₂ of only 72 on room air.

The chest x-ray film shows a prominent left ventricle, tortuous aorta, with clear lung fields. The mediastinum is not widened.

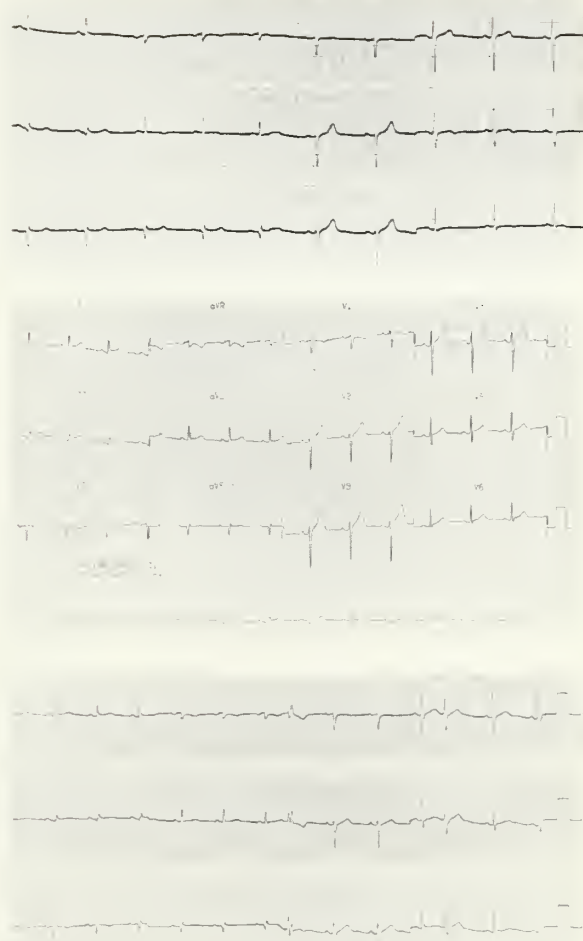
The electrocardiogram (Fig 1) shows inferior Q waves, consistent with a prior myocardial infarction. While they are not very wide, Q in AVF is 41 mm and greater than half of QRS, which meets criteria for prior myocardial infarction. Additionally, the R waves are diminutive until V₄, suggesting the presence of some anteroseptal damage. The rule of thumb is that there should be a slow but certain progression of R waves greater than 2 mm in V₃. A reading of anteroseptal damage is precarious, however, because of difficulty with electrode placement for recording anterior leads and other causes of poor R wave progression such as chronic obstructive pulmonary disease. It should be noted that the T waves in both the inferior and the anteroseptal leads do

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not suggest an acute process, although this could be misleading in a patient with chest pain of only one hour's duration. The repolarization abnormalities are most interesting in the lateral leads. The T wave is flattened in Lead I, inverted in AVL, V₅, and V₆ with upward coving of the ST segment in those leads. The clinical reading of possible inferior and anteroseptal damage from possible anterolateral ischemia is certainly appropriate. The possibility of pericardial and other processes would certainly be further down the list. The presentation of chest pain and an abnormal electrocardiogram are strongly suggestive of coronary artery disease. The patient was admitted to the hospital, where both sublingual nitroglycerin and narcotics were administered for the relief of chest pain which recurred without further electrocardiographic changes. Nitropaste was added. It should be added that the pain presumably did not respond to nitrates since narcotics were used as well.

The enzymes were significantly abnormal, but not indicative of an acute myocardial infarction. SGOT, LDH, and CPK were all elevated, but the myocardial fraction was normal and the LDH fractionations did not suggest myocardial damage. In addition, the electrocardiogram did not evolve to changes consistent with an acute myocardial infarction. The second electrocardiogram reveals the same R wave configurations as the first, but the anterolateral repolarization abnormalities previously noted have essentially resolved. It is possible in the evolution of an acute myocardial infarction to have a relatively normal T wave for short periods of time between an episode of ST elevation and T wave inversion. However, the T waves were already inverted on admission, and the lack of further evolution argues strongly against myocardial infarction.

On the second hospital day, the patient developed occasional pleuritic chest pain, which cannot be attributed directly to an acute myocardial infarction. He had a low-grade fever and remained hypertensive. A three component rub was heard. The electrocardiogram (Fig 2) shows definite ST elevation most pronounced in Leads I, II, L, and the precordial leads. Reexamination of the second electrocardiogram shows a mild ST elevation and possibly some mild PR depression. Both are consistent with pericarditis, and the diagnosis of pericarditis is inescapable with the findings of pleuritic chest pain, ST elevation on the electrocardiogram, and a three component rub. The laboratory findings were nonspecific and consistent with an acute inflammatory pro-



Figs 1-3. Serial electrocardiograms on the first, second, and sixth hospital days

cess.

The next major event was an episode of syncope which occurred after a bowel movement. While a vasovagal episode alone could cause syncope, it seems unlikely that vagal tone could explain the severe abnormalities in a man without a history of prior episodes. Classically, right coronary ischemia is associated with SA and AV nodal ischemia and excess vagal tone. The electrocardiograms, however, do not clearly define an acute infarction or active ischemia in the distribution of the right coronary artery. Despite the syncopal episode, the patient was quite well the following day, and the rub had disappeared. His electrocardiogram (Fig 3) revealed some premature contractions which appeared to be atrial with classic right bundle adherence and persistent ST elevation. Atrial arrhythmias are not unexpected and, in fact, are very common with pericarditis. The patient had another collapse, again after a bowel movement, with a fatal outcome. Of particular note is the intractable sinus bradycardia which

initiated the final arrest.

Coronary disease clearly needs to be considered in the differential diagnosis. An acute myocardial infarction is one possible consideration after episodes of chest pain related to unstable coronary circulation. His electrocardiograms strongly suggest prior myocardial damage, despite the lack of clinical history. He had risk factors, including a family history, hypertension, and a history of smoking. However, there are several reasons for discarding coronary disease as the primary cause of death. The patient had clearly documented pericarditis. Although pericarditis is a well-known complication of transmural infarctions, it is not a common complication of nontransmural or non-Q wave producing infarctions. Moreover, he had no evidence of an acute myocardial infarction as a basis for explaining the pericarditis. The enzyme elevations are presumably due to causes other than a cardiac source.

We should also consider multiple pulmonary emboli. This is a difficult diagnosis to make before death. It is a well-known complication of chronic congestive heart failure, found frequently in patients at the time of autopsy. However, multiple pulmonary emboli are rarely diagnosed on a clinical basis. The PO_2 was not extremely low, and he had no evidence of right heart strain by electrocardiogram. His respiratory rate, slightly elevated on admission, was normal on the second hospital day. Pericarditis is a possible, but rare, complication of pulmonary emboli from contiguous pleuritis associated with pulmonary infarction. However, his chest x-ray studies and clinical well-being argue strongly against the diagnosis of multiple pulmonary infarctions. At no time, other than upon admission, did the patient have dyspnea, a symptom almost invariably associated with multiple pulmonary emboli and his chest x-ray findings remained unchanged throughout his hospitalization.

The pericarditis suggests a differential diagnosis of the other possible processes involved. The differential diagnosis of acute pericarditis is extensive. Infectious causes of pericarditis include viral, tuberculous, bacterial, mycotic, and parasitic etiologies. The common syndrome of viral pericarditis, or what we presume to be viral pericarditis, is more commonly morbid and rarely mortal. In fact, it often is called "benign pericarditis." Importantly, there was nothing to suggest an evolving severe inflammatory process. Tuberculous pericarditis is less acute. A suppurative pericarditis may have a malignant course, but it is a very rare disorder in the absence of a con-

tiguous infection, unless, as in open heart surgery, the pericardium has been violated. Subacute bacterial endocarditis should be considered, as pericarditis can complicate that process. The patient did not have the constitutional symptoms of weight loss, fever, or clear-cut evidence of an intravascular infection. There were no murmurs and no evidence of embolic phenomenon to suggest endocarditis. Other causes of infectious pericarditis include esophageal perforation and an intrathoracic infection, neither of which is present here. Mycotic and parasitic infections can be disregarded, as the host is not immunologically impaired. Neoplasm can cause pericarditis either from contiguous spread, metastatic spread, or, rarely, as a primary pericardial tumor. The absence of constitutional signs and lack of evidence of a primary tumor argue against malignant pericarditis.

Dressler's syndrome appears most commonly two to ten weeks after myocardial infarction. Sizeable amounts of fluid may accumulate, and tamponade is a significant complication of this syndrome. However, there are several problems with this diagnosis. There is no definite history of a recent antecedent myocardial infarction, as the age of the presumed prior damage by electrocardiogram is unknown. In addition, his clinical course did not follow severe pericarditis with fluid accumulation, but rather that of a benign, incidental pericardial inflammatory process followed by a totally catastrophic event on the sixth day. There was no dyspnea, orthopnea, increase in heart size on chest x-ray examination, or physical findings to suggest Dressler's syndrome.

Hemopericardium may be caused by trauma, perforation of the ventricle, anticoagulant therapy, or dissecting aortic aneurysm.

There are a number of features in the presentation which are consistent with dissection of the proximal aorta. Antecedent hypertension was present. The disease occurs three times as commonly in males. Although the initial presentation was not associated with heavy lifting, he had two episodes of syncope in the last two days of his hospitalization, including the final episode, which may have been associated with straining of stool. This has been reported in 14 per cent of patients with dissections. He did not have severe pain as is commonly associated with acute dissection. He could have had a subacute dissection or redissection, which could explain, as part of a single process, his initial neurological episode three years earlier. In one series, syncope without focal neurological signs occurred in six patients,

five of whom were found to have dissection into the pericardial cavity. Vasovagal manifestations are common, as are neurological complications. Dissection of a proximal aneurysm extended to the coronary arteries results in myocardial infarction in one to two per cent of cases, with rupture into the pericardium occurring much more commonly. The presentation of severe heart failure is a complication of severe aortic regurgitation, for which there is no evidence in this particular case.

In summary, I believe that this patient had a proximal aortic dissection which was of a chronic nature with rupture into the pericardium resulting in his demise. I would postulate that a prior dissection or prior manifestation of the same dissection is the etiology for his neurological symptoms and continuing symptoms during the previous three years. In addition, I believe that he had atherosclerotic coronary disease as well as findings of chronic hypertension, the latter resulting in his predisposition to dissection. I cannot exclude right coronary artery involvement as the cause of his terminal severe bradycardia.

Doctor Drew's Diagnosis

Proximal aortic dissection with rupture into pericardium

Atherosclerotic coronary disease

Essential hypertension

Pathological Discussion

Carl H. Critz, MD*: At autopsy, external examination revealed a well-developed, well-nourished white man with plethora of the upper chest, neck, and face. The pericardium was tense and contained 620 g of fluid and clotted blood. The underlying pericardium showed a fibrinous pericarditis. The adventitia of the ascending aorta was distended and hemorrhagic with no discrete rupture site. The ascending aorta showed a circumferential medial dissection forming a flat circumferential false channel containing fluid and clotted blood. The intimal surface of the ascending aorta was smooth. A ragged, crescent-shaped, intimal-medial tear, 2.5 cm by 0.6 cm in size, was present on the posterior aortic wall, located 1.4 cm above the non-coronary cusp communicating with the dissection (Fig 4). The proximal extent of the dissection was the right coronary ostium which was not occluded and reached within 0.5 cm of the left coronary ostium. The superior extent of dissection was 3.5 cm up the innominate artery and 0.5 cm up both the left carotid and left subclavian arteries. The dissec-

* Senior Resident, Department of Pathology, Rhode Island Hospital

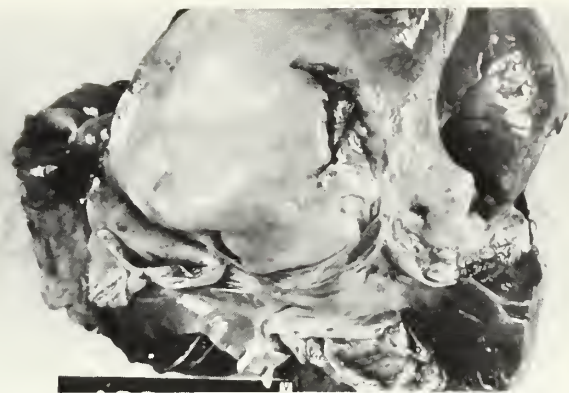


Fig 4. Posterior aortic wall with intimal-medial crescent shaped tear

tion extended inferiorly as a 0.3 cm wide track in the posterior aortic wall to the region of the left renal ostium, where it expanded to a 1.5 cm by 1.0 cm by 0.5 cm mural hematoma without re-entry or rupture.

Coronary atherosclerosis was moderate with a postero lateral patch of myocardial fibrosis suggestive of healed myocardial infarction. There was no left ventricular hypertrophy (cardiac weight 350 g) and no evidence of acute myocardial infarction. Aortic atherosclerosis was mild for age, and only mild arteriolonephrosclerosis was present. On histological examination, the intimal tear showed fibrin and early fibroblastic repair reaction in the torn media. The dissection was located at the junction of the middle and outer third of the media. Focal areas of grade I cystic medial necrosis were present, but not associated with the region of dissection. Laminar medial necrosis was present at several levels confined to the mid-media and was not involved in the dissection. There was focal elastic fragmentation.

The most common complication of aortic dissection is rupture, which usually occurs in the ascending aorta. Since the pericardial reflection reaches the innominate artery, 89 per cent of ruptures enter the pericardium, resulting in cardiac tamponade. The adventitia which forms the outer wall of the false channel is leaky, and the surface may weep a serosanguinous effusion, which elicits inflammation in the pericardium or pleura prior to rupture. Hirst reported a series of aortic dissections in which six had pericarditis and four per cent had premortem rubs.¹

Anatomic Diagnosis

Aortic dissection, type A, with fibrinous pericarditis, pericardial rupture, and cardiac tamponade.

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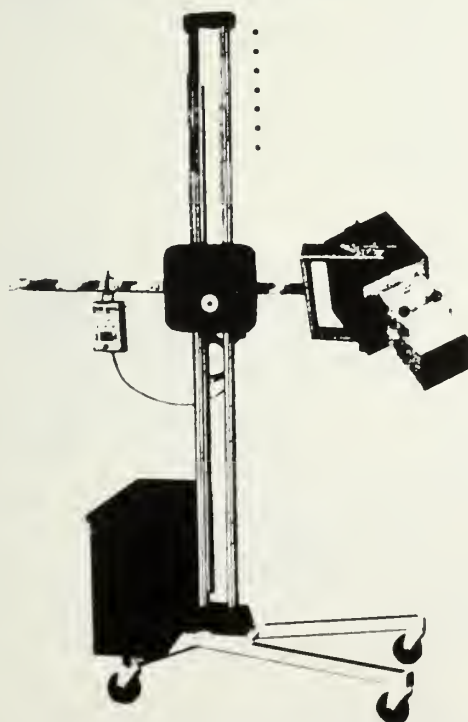
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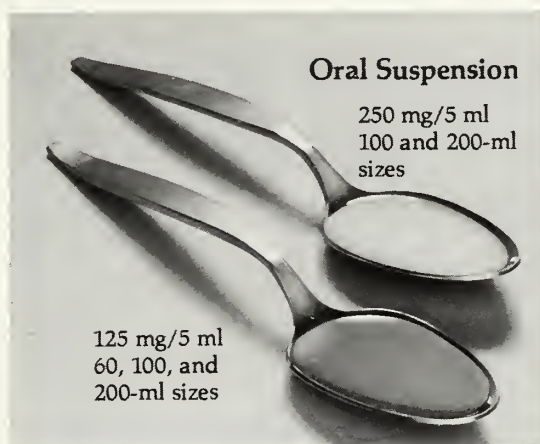
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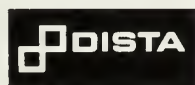
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BRIEF SUMMARY PROCARDIA® CAPSULES (nifedipine)

For Oral Use

INDICATIONS AND USAGE: I. **Vasospastic Angina:** PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation, 2) angina or coronary artery spasm provoked by ergonovine, or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. **Chronic Stable Angina (Classical Effort-Associated Angina):** PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA.

WARNINGS: Excessive Hypotension: Although in most patients, the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out.

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients, usually receiving a beta blocker, have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General: Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug Interactions: Beta-adrenergic blocking agents: (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates: PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis: Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Carcinogenesis, mutagenesis, impairment of fertility: When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy: Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients, transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication. Additionally, the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature.

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine. PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x10) (NDC 0069-2600-41). The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77° F (15° to 25° C) in the manufacturer's original container.

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Contraindications: Known hypersensitivity to flurazepam HCl; pregnancy. Benzodiazepines may cause fetal damage when administered during pregnancy. Several studies suggest an increased risk of congenital malformations associated with benzodiazepine use during the first trimester. Warn patients of the potential risks to the fetus should the possibility of becoming pregnant exist while receiving flurazepam. Instruct patient to discontinue drug prior to becoming pregnant. Consider the possibility of pregnancy prior to instituting therapy.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

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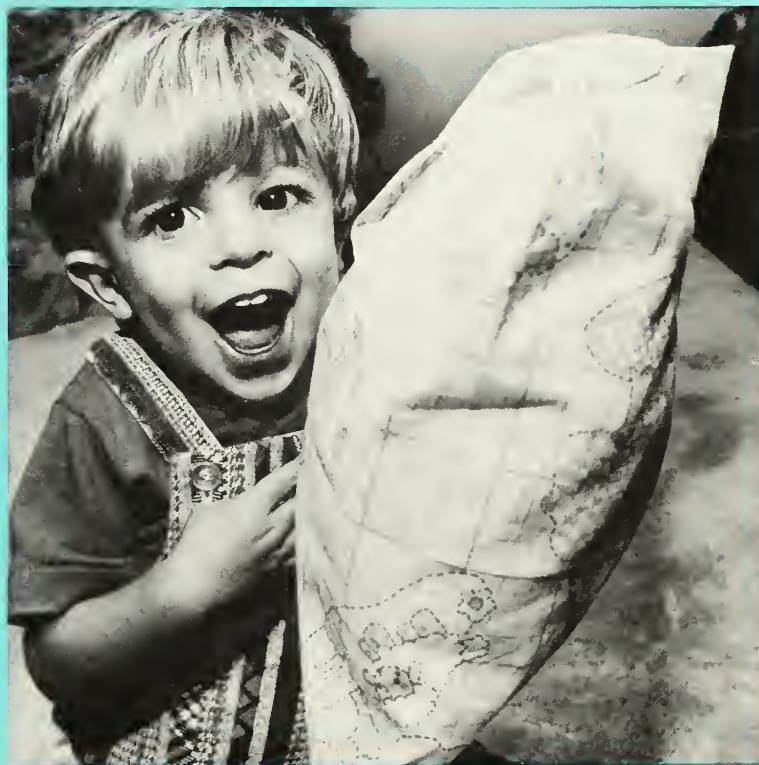
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Rhode Island Medical Journal

February 1984
Volume 67, Number 2

**DISPLAY
SHELVES**

**Mikey Almeida of Tiverton,
Rhode Island — See Page 59**



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HAVE YOU HEARD? . . .

Newsletter

RHODE ISLAND MEDICAL SOCIETY

February 1984

Charles P. Shoemaker, Jr., MD, President

Wendy J. Smith, Editor

HEALTH DEPARTMENT REPORTS TO HOUSE OF DELEGATES ON PHYSICIAN MANPOWER

The state currently lacks a "forum which involves all the major players in Rhode Island to discuss problems like physician manpower," William J. Waters, PhD, Rhode Island Department of Health, told the Society's House of Delegates last month. The manpower issue was scheduled as a discussion item immediately before the January 18 meeting in response to growing concerns about a perceived oversupply of physicians. In addition to Waters, present from the Department were John Tierney; Donald C. Williams, MPH; Robert Marshall, PhD; and Charles McConnell, PhD.

The health department officials also told the RIMS delegates that:

- While the estimated physician/population ratio throughout the country is expected to reach 230/100,000 by 1990, the comparable figure for Rhode Island may well exceed 270/100,000. Rhode Island currently ranks eighth among the states in terms of physician/population ratio.
- In 1980, the Graduate Medical Education National Advisory Committee (GMENAC) concluded that there will be an estimated 70,000 "surplus" physicians nationwide by 1990, and 140,000 by 2000. The Committee, which functioned under the US Department of Health and Human Services from 1976 to 1980, was charged with determining the "ideal" number of physicians that would be required for each specialty and subspecialty.
- When the GMENAC "optimum" specialty projections were measured against 1980 Rhode Island manpower figures, the latest available, the presence of an oversupply was apparent in the following specialties: general pediatrics, general internal medicine, cardiology, general surgery, orthopedic surgery, and neurosurgery.

There was a shortage, however, of family physicians, allergists, pulmonary disease specialists, neurologists, psychiatrists and child psychiatrists, radiologists, pediatric allergists and cardiologists, thoracic surgeons, and preventive medicine specialists.

The following specialties were seen as being "nearly balanced" between the supply of physicians and the requirements for their services: dermatology, gastroenterology, obstetrics/gynecology, ophthalmology, pathology, and plastic surgery.

- It is difficult to measure the impact of the Brown University Program in Medicine and its affiliated training programs, the health department officials said. Of the 390 residency training positions in the Brown system in 1982, an estimated 27 per cent were filled by graduates of the Brown medical program. Between 20 and 30 per cent of all residents who train in Rhode Island subsequently establish practices in the state.

(continued)

PHYSICIAN MANPOWER (continued)

- The 1983 state health plan calls for developing a balance between the "supply and need" for physician manpower. The plan specifically recommends that the \$1.1 million in direct state support for the Brown program should emphasize primary care services. Moreover, third party payers, according to the plan, should consider reviewing the impact of their indirect support of residency training programs.

Noting that the "figures clearly demonstrate the need for some type of action," Waters called for a statewide forum to include representatives from the practice community, Brown, Blue Cross & Blue Shield, and the hospitals to deal with such potentially troublesome problems as the impact of a "physician glut." He also suggested that the Society consider participating in a manpower survey with the Department to obtain updated information. The last survey of physician manpower in Rhode Island was conducted in 1980.

ANNUAL MEETING SCHEDULED FOR MAY 23

The Annual Meeting of the Rhode Island Medical Society will be held Wednesday, May 23, 1984, at the Providence Marriott, Society President Dr Charles P. Shoemaker, Jr., recently announced. It will feature the annual session of the House of Delegates, and formal presentations by Drs Joseph Boyle, President-Elect, American Medical Association, and Robert G. Petersdorf, 1984 Chapin Orator. Margaret Heckler, Secretary, US Department of Health and Human Services, has been invited to the dinner as a keynote speaker.

Invitations and reservation forms will be in the mail in early April.

INCIDENCE OF MALPRACTICE SUITS CONTINUES TO CLIMB

It was reported at the January 18 meeting of the Rhode Island Medical Society House of Delegates that another "malpractice crisis" appears imminent as one of every three Rhode Island physicians currently faces a pending suit. President-Elect Dr Paul J.M. Healey, who serves as chairman of the Ad Hoc Committee on Tort Reform, also told the House that the frequency and size of award settlements have increased substantially.

The committee has developed a 1984 legislative campaign targeted toward several limited objectives, including elimination of awards for "pain and suffering," a recision of the current 12 per cent interest penalty added to all awards, and a system of structured payments. In addition, an issue of the Rhode Island Medical Journal will focus on the problem, and an educational seminar on risk management is planned for next fall.

In other actions, the House of Delegates:

- approved a petition by the Rhode Island Urological Society for designation as an "officially recognized specialty society" with full voting privileges in the House.
- approved a policy statement on representation of the Rhode Island Medical Society before the General Assembly and other government agencies.
- noted that discussions are continuing with representatives of New England Bell to investigate the feasibility of implementing a 911 emergency number

HOUSE OF DELEGATES (continued)

system in Rhode Island. The state is one of the few jurisdictions in the country without a 911 system.

- received a report that the trustees of the Caleb Fiske Fund have selected "A Current Technological Innovation and Its Impact on Medicine" as the topic for the 1984 Fiske Fund Competition. The 1984 prize will be an award up to a maximum of \$2,500.
- received a report which indicates that total Society expenditures for 1983 were \$441,696 and total receipts were \$404,038. A certified audit of the Society's financial records will be performed later this spring. As of December 31, 1983, there were 1,375 members of the Rhode Island Medical Society, including 17 student members and 220 members who are dues exempt because of their age, disability, retirement, or status as clergy. The Society gained 61 new members during the past year.

PERIPATETICS

Members in the news include:

- Edwin N. Forman, MD, a Providence pediatric oncologist, has been elected president of the Rhode Island Division of the American Cancer Society. The new president-elect is Francis J. Cummings, MD, also of Providence.
- St. Joseph Hospital has named Allan A. DiSimone, MD, Johnston, as director of its department of surgery.
- Tumkur B.N. Kumar, MD, Pawtucket, has been elected a fellow of the American College of Chest Physicians.
- The American College of Surgeons recently inducted Daniel E. Wroblewski, MD, a Providence colon and rectal surgeon, as a fellow.
- New medical staff officers at Roger Williams General Hospital include Howard S. Sturim, MD, president; Mario Tami, MD, vice-president; Philip O'Dowd, MD, secretary-treasurer; and Anthony F. Testa, MD, delegate to the Executive Committee. All are from Providence.
- The Staff Association of Rhode Island Hospital also has elected its new officers for 1984: John Lathrop, MD, president; Paul Sydlowski, MD, president-elect; Joseph Lombardozzi, MD, vice-president; and Kenneth E. Liffmann, MD, treasurer. Members at large of the Executive Committee include Jacek Franaszek, MD; Mary D. Lekas, MD; Lawrence Colasanto, MD; and Boyd King, MD.

PRACTICE MANAGEMENT PROBLEM OF THE MONTH:

ARE SERVICE BUREAUS A VIABLE ALTERNATIVE TO AN IN-HOUSE COMPUTER?

For some office practices, a service bureau may provide an acceptable compromise between a manual system and an in-house computer. Service bureaus, which originally offered a service now known as "batch processing," first began to appear in the mid-1960s in response to the growing administrative burden of insurance

claims forms. As computer technology advanced and practice requirements became more sophisticated, service bureaus initiated time-sharing services which link remote terminals in the physician's office with a central computer at the bureau.

How does batch processing work?

Under a batch processing service agreement, the data on patients, the services performed, and insurance claims are recorded for a specific period and transmitted to the service bureau in a batch by mail or delivery. Usually, batch processing by an outside organization: 1) improves control of the practice by providing reports on financial activity and practice productivity; 2) reduces workload by transferring the preparation of patient statements, insurance forms, and financial reports elsewhere; and 3) provides the advantage of computer support without many of the responsibilities and expense of purchasing a computer.

Many physicians, however, especially those who require prompt service, find that batch processing is too slow and cumbersome for their needs. The updated records are available only when the processing cycle at the service bureau is complete and the information is returned to the practice. Moreover, errors and omissions discovered during the editing process at the bureau must be returned for correction and verification.

For some practices, other disadvantages may be even more significant. Among these are the possibility of losing data between the practice site and the bureau, potential breaches of patient confidentiality, and the lack of immediate access to patient records and financial data during the processing cycle. Finally, as most batch processing arrangements are billed on a piecework formula, the service can be comparatively expensive, even for practices with few transactions.

What about time-sharing?

With a "time-sharing" arrangement, a central computer at the service bureau is linked to different practices through computer terminals at each office and dedicated telephone lines. It offers significant advantages to batch processing as data can be transmitted immediately and the physician may obtain patient information at any time. In its most sophisticated form, a time-sharing service closely resembles an in-house computer, except that high volume material usually is printed at the service bureau and delivered to the practice. Some time-sharing services, however, transmit the processed data back to the practice site for printing.

There are some disadvantages, including the storage of patient data at a remote site not under the direct control of the practice. The service also involves a significant investment in continuing costs for communication equipment and service charges. For each video display terminal, the monthly rental cost may be as high as \$450. The monthly processing fee, like batch processing, is determined by the volume of transactions and can accumulate quickly depending on the type of practice.

For these reasons, batch processing and time sharing may be the solution for extremely specialized practices with a low volume of daily transactions. Practice management experts recommend that the service bureau should be selected with extreme care. Physicians should limit their choices to bureaus which have been in business for at least three years and specialize in medical or dental practices. The bureau should be asked to supply the names of references (preferably physicians with similar practices), provide samples of the forms to be used by the practice, and provide adequate back-up in case of equipment malfunction.



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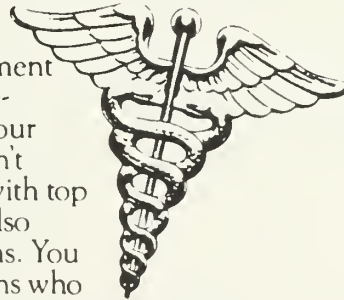
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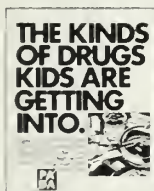
Do You Know an Impaired Physician?

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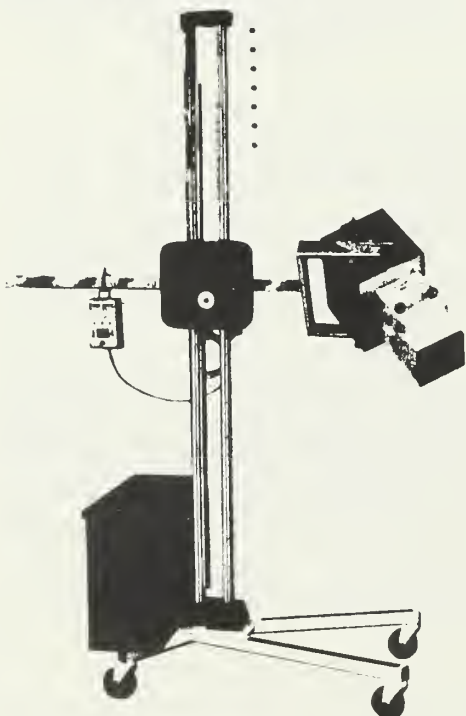
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83 **Development of the Protocol for Organ Procurements at Rhode Island Hospital**

Increasing Attention Is Given to Procurement and Transplantation of Kidneys, Livers, and Other Organs

Robert A. DeNoble, MBA

COVER:

Mikey Almeida of Tiverton, Rhode Island, who received a liver transplantation in 1983. For the past year, the Society has participated in an educational program intended to stimulate public awareness of the importance of organ donations. As part of this effort, the February issue features an analysis of organ transplantation from a variety of perspectives. We are especially pleased that the editorial has been contributed by the Hon. J. Joseph Garrahy, Governor, State of Rhode Island and Providence Plantations. See page 61.

Photograph provided courtesy of The Providence Journal.



MASTER HEALTH UPDATE

JANUARY 1984

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MARKETING UPDATE

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ENROLLMENT EPIDEMIC

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EDITORIALS

A Simple Act of Giving

During the past year, the Society has participated in a program designed to increase public awareness of the importance of organ donation. Organized under the aegis of the Governor's office, the program is being implemented by the Life Underwriters Association of Rhode Island with the cooperation of the Rhode Island Medical Society; the Department of Health; the Rhode Island chapters of the American Academy of Pediatrics and American College of Emergency Physicians; the Hospital Association of Rhode Island; the Rhode Island Lions Sight Foundation; the Rhode Island Kidney Foundation; the Rhode Island Association for the Blind; Donor Alert; and the New England Organ Bank. The theme of the program, "a simple act of giving," has been publicized on local television broadcasts and before civic organizations throughout the state.

While liver transplantations have stimulated an unprecedented degree of public interest, the need for other organs remains acute. According

to the New England Organ Bank, more than 1,000 persons in the six-state New England region would be suitable candidates for renal transplantation if a sufficient number of kidneys were available. An estimated 130 New Englanders are awaiting corneal transplants, and an unknown number could potentially benefit from skin and bone transplantations.

As part of the public education campaign, this issue of the *Rhode Island Medical Journal* focuses on organ procurement from several perspectives. Additional information as to the specific criteria for organ donation is available from the Boston-based New England Organ Bank. It maintains a 24-hour "hotline" at 617/277-8500; collect calls are accepted. The Rhode Island Department of Health has produced an informational brochure which is suitable for distribution to patients and a cardboard poster appropriate for office display. Both are available from the Governor's Citizen Information Service (401/277-2494).

The Importance of Public Involvement in Organ Procurement

I should like to take this special opportunity to thank the representatives and members of the Rhode Island medical community for their participation in our Organ Donor Awareness Program. We, in Rhode Island, have witnessed the plight of families seeking life-saving organs for their seriously-ill loved ones. Rhode Island has reacted in its usual humanitarian way. A group of volunteers from many walks of life have come together through the efforts of the Rhode Island Life Insurance Underwriters Association to address the problem of this shortage of organs for transplantation.

Our task, and the goal of this program, is to help make certain that every patient who needs an organ for a transplant is afforded that opportunity. Although the need for livers has received

much publicity of late, the inadequacy of the supply of kidneys and other organs is of equal concern. About 20,000 potential donors die each year; yet 90 per cent of them do not donate.

This awareness campaign is an attempt to increase the donation of organs by educating health care professionals and the public about the critical need for organ donations. The purpose of the campaign is to encourage families to think about donation before a tragedy occurs. It is hoped that the medical community will come to understand better the donation procedures and responsibilities so that they may provide the necessary support and guidance to families who need it.

This may be the first campaign anywhere in the nation which addresses the need to increase awareness by both the public and health profes-

sionals of this critical health issue. Once again, Rhode Island is in the forefront in responding to the needs of our citizens. Equally significant is the fact that in Rhode Island we have brought government, private groups and individuals, and leaders in the health field together to make a serious impact on this situation.

I should like to thank the numerous public and private agencies which have contributed to this effort. In addition to the outstanding commitment of the Life Insurance Underwriters Association, especially John Corbishley, who is coordinating this effort, officials of the Rhode Island Medical Society, the Rhode Island Chapter of the American Academy of Pediatrics, the Rhode Island Chapter of the American College of Emergency Physicians, the Hospital Association of Rhode Island, the Rhode Island Departments of Health and Transportation, the New England Organ Bank, the Rhode Island Association for the Blind, the Rhode Island Foundation, the Lion's Sight Foundation, the Kidney Foundation, our local media, and many individual volunteers

are participating in this campaign. In just a few months, they have designed the means for increasing information and awareness among the general public and among our health professionals.

The Rhode Island Medical Society is to be commended in a special way for its leadership in the effort to inform and assist the physicians of the state. The dedication of this issue of the *Rhode Island Medical Journal* to the discussion of organ donation exemplifies this leadership and a unique commitment to community responsibility. I join with the medical society in urging the entire health care community to become familiar with the need for and importance of organ donation. It is to you that many of us will turn for guidance and direction as we make our personal decisions to donate.

J. Joseph Garrahy
Governor
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A WORD TO THE WHYS

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PRESIDENT'S PAGE



Public Awareness Campaign and Long-Range Planning Activities

This issue of the *Rhode Island Medical Journal* focuses exclusively on the procurement and transplantation of human organs. As few of us are directly involved with transplant procedures, it is tempting to set the *Journal* aside and get on with something else. Because of rapid developments in the field of organ transplantation, however, we are becoming more involved on a daily basis. At the very least, *The Providence Journal* has reminded us constantly of the advances made in heart and liver transplantations.

As practicing physicians, we must remain abreast of recent clinical advances for two reasons. The first is to present current information to patients who may be appropriate candidates for transplantation due to organ failure. Secondly, the number of inquiries from the relatives of potential donors about the possibility of organ donation are increasing, primarily as the result of widespread publicity in the media. Unfortunately, many of us are not aware of the criteria for transplantation, let alone the logistical procedures involved.

Both physicians and the public are becoming more cognizant of the significance of the problem. As physicians, we should educate both ourselves and our patients. We owe it to our patients to be informed of the potential benefits of transplants, or, if dealing with an unfortunate victim, to offer the family the consolation of benefiting another person through organ donation.

Long-Range Planning and the Society

At its December meeting, the Council authorized the president to appoint a Long-Range Planning Committee. The action was taken as a result of a proposal from Washington County to extend the term of the president and to consider remuneration as partial compensation for lost practice time. Another item to be considered by the new committee is the current method of membership representation through the district and county medical societies. Because concerns have been voiced about the level of activities in some county societies, some members have advocated repre-



Charles P. Shoemaker, Jr., MD

sentation through the state specialty societies as a viable alternative.

The length of office and compensation are both difficult issues to address. With the "right" person, it would make sense to extend the term of office since a certain amount of momentum is lost with the transition of officers each spring. It must be noted, however, that the continued growth of the Society depends on the ability of its leaders to respond to rapidly changing developments and a constant stream of proposals from the State House. Because of the range of problems facing us, new people with fresh ideas must be involved in the process.

The issue of representation is even thornier. It has become increasingly apparent that many physicians feel more closely tied to their hospital staffs and specialty organizations than to their county medical societies. This does not present much of a problem in such counties as Newport where the hospital medical staff and the county society are nearly the same organization. Within

larger district societies, however, it is likely that the delegation to the Council and House of Delegates will include representatives from only a few of the large metropolitan hospitals. While many of the problems faced by each hospital staff are unique to that institution, others affect all physicians, regardless of their specialty or hospital affiliations. In recent months, these issues have included such problems as the "physician glut," closed medical staffs, the Joint Commission on the Accreditation of Hospitals (JCAH) standards, and "do not resuscitate" orders. In response to

the concerns of hospital staffs, the AMA has established a section council with full voting privileges. It may also be appropriate for the Society to consider establishing more formal linkages with hospital medical staffs throughout the state. Specialty societies already have voting representation within the House of Delegates.

If the Society is to remain viable, we must organize to meet the challenges of tomorrow. Your reactions to these various suggestions would be helpful as we consider how to restructure our priorities.

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Organ Procurement: The Role of the New England Organ Bank

Regional Organ Bank May Well Serve as a Model for a National Procurement System

Judith Shaw Lucier, RN
James W. Bradley, BS
Sang I. Cho, MD

The New England Organ Bank (NEOB) was established in 1968 as a regional organ procurement agency, as the result of a collaborative effort by the 13 renal transplant centers in New England to promote the procurement, preservation, and equitable distribution of cadaveric kidneys for transplantation.¹ A private non-profit organization, it is not affiliated with any individual hospital or university. The organ bank is governed by a board of trustees which is broadly representative of the regional interests concerned with transplantation.²

Three internal divisions — administration, tissue typing, and procurement and preservation — are responsible for its day-to-day operation. The tissue typing laboratory performs the necessary histocompatibility testing and maintains monthly serologic results for the nearly 400 patients currently awaiting cadaveric renal transplant. A computerized system will quickly match serologic data from a donor to determine if a local recipient is compatible. If not, the New England Organ Bank maintains access through a national system, the United Network for Organ Sharing, to share kidneys with other centers.

The procurement and preservation division

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has responsibility for the entire procurement process. Coordinators and specialists are available to assist hospitals with identifying and evaluating potential organ donors, providing on-site consultation on the medical maintenance of donors, and obtaining consent from the next-of-kin.³ Moreover, NEOB staff members provide technical expertise and support with the actual procurement procedure and preservation of the excised organ, and are responsible for transferring the organ to the recipient transplant center, either locally or nationwide.

Procurement Program Methodology

Coordinators from the New England Organ Bank are available to help establish procurement programs within individual hospitals and to provide educational programs on the donation process for hospital personnel. This is accomplished through a systematic two-phase approach that was devised four years ago in collaboration with the Centers for Disease Control.⁴

To determine the size and characteristics of the potential organ donor pool, the first step consists of a retrospective record review of hospital deaths in critical care areas. The second stage involves an educational program designed to develop a commitment to organ retrieval among the professional and administrative hospital staff; and active surveillance, or the continuous process of identifying and reporting donors in sufficient time to make retrieval possible.⁵ Such key hospital staff as nephrologists, neurologists, neurosurgeons, critical care nurses, nursing supervisors, chaplains, and social workers are encouraged to participate.

With this organized approach to organ procurement, the organ bank was able to respond effectively and rapidly to the recent significant

increase in the number of referrals from hospitals which had identified potential organ donors. During the period from October 1982 until September 1983, the procurement and preservation division helped facilitate the retrieval of 314 kidneys, nine livers, nine hearts, and two pancreata for transplantation.

Donor Identification and Evaluation

Ideal organ donors are previously healthy individuals who have suffered such an irreversible brain injury as head trauma, intracranial or subarachnoid hemorrhage, primary brain tumor, cerebral anoxia from any cause, or cerebrovascular accident. When it becomes apparent that a

Table 1. Organ Donation Criteria

Brain death as demonstrated by:
— apnea requiring respirator support
— no brain stem reflexes
— no response to painful stimuli
— no spontaneous movements
— confirmatory testing at discretion of attending physician and local guidelines
Age:
— newborn to 65 years (kidney)
— 6 mos to 45 years (liver)
— 15-40 years (heart)
Effective cardiovascular function
No history of significant hypertension or diabetes
No history of malignancies other than primary brain tumor
No systemic infection
No recent wound or surgery to gastrointestinal tract

patient has satisfied or shortly will meet acceptable criteria for brain death, the option of organ donation may be explored (Table 1).

During the initial call to the organ bank, preliminary information will be collected on the name, age, cause of death, blood type and recent laboratory values, and status of the declaration of death. A procurement coordinator will come to the hospital to evaluate the patient further. If appropriate, depending on the cause of death and course of hospitalization, the possibility of donation of extrarenal organs will be explored (Table 2). The availability of suitable recipients for the other organs will be determined before an extended donor evaluation is initiated.

A 24-hour telephone service was initiated in 1982 to provide information on extrarenal transplant centers and the specific requirements of individual recipients. It has greatly facilitated the locating of heart, liver, and heart-lung donors for patients in urgent need of these organs. Initially started by the University of Pittsburgh to locate

liver donors, the service currently is sponsored by the North American Transplant Coordinators Organization.

Obtaining Consent

The evaluation of the potential donor may be conducted before final consent has been obtained from the family. In addition to assuring that the patient does satisfy the criteria for donation, this will provide the family with more time to acknowledge and adjust to the terminal condition of their loved one.

Unless the family has initiated the idea of donation, as occurred with 15 per cent of the donations in 1982, it is advisable to wait until the certainty of brain death is evident before introducing the topic. Families who have any hope for recovery will not give consent. The person who introduces the subject should be one who is famil-

Table 2. Guidelines for Organ Donor Evaluation

<i>Kidney:</i> ABO; CBC; BUN; creatinine; electrolytes; arterial blood gases Hb _g Ag; VDRL or RPR; urinalysis; cultures of sputum, urine, and blood
<i>Liver:</i> same as kidney, and SGOT, SGPT, total and direct bilirubin, weight, and abdominal girth
<i>Heart:</i> same as kidney, and CPK, EKG, weight, and abdominal girth; cardiac consultation may be recommended
<i>Pancreas:</i> same as kidney, and serum amylase

iar with brain death and feels comfortable with organ donation, who can convey the need for organs, and who can communicate the benefits experienced by donating families.

The recent publicity about the need for organs has eliminated much of the fear and mystique about organ donation, and the rate of consent is greater than 85 per cent at the present time, an increase of more than 30 per cent over last year. In addition to providing a positive outcome to an otherwise tragic situation, donation has resulted in substantial emotional consolation to donating families.

Donor Management

When it becomes clear that the patient meets acceptable donor criteria, certain measures must be utilized to assure the viability and quality of the organs. While the final decisions for medical management of the patient are directed by the attending physician, the staff of the organ bank may offer suggestions as to the maintenance of the potential donor. Coordinators also are available to provide on-site consultation and other

assistance if problems occur.

Restoration of the patient to a normal or slightly overloaded fluid status is of primary importance, as is maintenance of adequate blood pressure (> 90 systolic) and oxygenation. If the patient remains hypotensive in spite of aggressive fluid therapy, dopamine administration may be initiated, although high doses may preclude the eligibility of the patient to donate extrarenal organs.

The prevention of infection will require continued customary precautions and aseptic techniques, and daily cultures of sputum, urine, and blood will be necessary. If a local infection is present, the use of nephrotoxic antibiotics should be avoided.

Declaration of Brain Death

The declaration of brain death on the basis of neurological criteria will be directed by the attending physician following guidelines established by the hospital or state.⁶ The pronouncement in the chart should include the date, time, and full description of the criteria used. The use of such confirmatory testing as an electroencephalogram or four-vessel angiography will depend on the cause of death and be performed at the discretion of the attending physician. In the absence of such confirmatory testing, an observation period of 12 to 24 hours is recommended. While the completion of the death certificate is not a prerequisite for donation, it is highly recommended to assure the operating room personnel that all medical and legal requirements for the procurement of organs from a heart-beating cadaver have been achieved.

The consent of the medical examiner is required in all accidental or suspicious deaths, and in all cases of organ procurement in Rhode Island.

Donor Surgery

The donor nephrectomy, hepatectomy, cardiectomy, or all three procedures will be scheduled as soon as all legal requirements for donation have been completed, and the procurement teams have determined their travel arrangements. Extrarenal organs procured for centers outside the region, as well as for New England centers with comparatively new programs, may require two or more teams to meet at the donor hospital.

Depending on the procedures performed, surgery will last from three to five hours, during which period maintenance of vital functions will be monitored by anesthesia personnel. The blood

gases, electrolytes, temperature, and vital signs are carefully evaluated and the administration of blood, intravenous fluids, and certain medications are important to the optimal stability of the patient and condition of organs during handling.

Once final dissection and excision of the organs is complete, they will be immediately cooled and perfused with iced Ringer's lactate or an intracellular solution. After further examination, the heart and liver will be placed in a sterile bag and packed in ice, and the kidneys will be placed on a pulsatile preservation machine. The spleen and several lymph nodes will be obtained and sent to the tissue typing laboratory for cross-matching and histocompatibility typing. The termination of life support will occur after the organs have been removed from the body, and the procurement members will be available to provide technical or emotional support, if necessary.

The teams will then depart for their respective locations. The heart and liver will be immediately transplanted into waiting recipients as the maximum cold ischemia time is limited to eight hours for the liver and four hours for the heart. Renal transplants will be performed within the next 36-48 hours. If acceptable recipients are not found among those on the New England list, the kidneys will be transported to those centers outside the region indicating the best match.

If the patient is a multiple or universal donor, the procurement of long bones for transplantation will be performed in the operating room following the nephrectomy. The procurement of eyes and skin will be performed in the morgue.

Follow-Up Procedures

The New England Organ Bank will contact hospital billing departments to arrange for financial reimbursement. All costs initiated by the organ bank for the evaluation and management of a potential donor, as well as all charges after the declaration of brain death, including operating room costs, are paid for by the New England Organ Bank to assure that the donor family does not receive that portion of the bill.

Once recipient transplants are completed, letters will be sent to the donor family, hospital staff, and other persons involved in the donation process to inform them of the outcome. While the names of recipients are not revealed, such information as age, geographic location, and some personal information will be shared in addition to the medical condition.

Conclusion

Each individual procurement system is tailored to meet the specific needs and requests of the hospital, and protocols can be formulated to reduce confusion and designate the appropriate hospital policies and implementation procedures. The development of a memorandum of agreement between the hospital and the New England Organ Bank has proven helpful in establishing a formal acknowledgment of the organ procurement program, and provides a basis for understanding the roles played by the attending physicians, hospital staff, and organ bank personnel in the retrieval process.

Public interest in organ donation has been heightened by recent clinical advances, especially with transplantations of the heart, liver, heart-lung, and pancreas; by the apparent success of cyclosporine as a major immunosuppressive

agent; and by the rapid development of extrarenal transplant centers in New England. In addition, discussions are continuing on the national level concerning the need for an effective program for the procurement and distribution of cadaveric organs for transplantation. It is important that a systematic approach to organ donation be employed to meet the needs of the community and its hospitals.

The New England Organ Bank recognizes its commitment to the region to provide quality organs upon which the lives of its citizens depend. It is this commitment and the successful cooperation of the several New England transplant centers which has made the NEOB a productive and cost-effective regional organ procurement agency, and one which is regarded as a potential model for a national system.

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The NIH Consensus Development Conference on Liver Transplantation

Panel Finds Liver Transplants To Be Beneficial under Appropriate Circumstances for Some Patients

Charles E. Millard, MD

In June 1983, the National Institutes of Health (NIH) organized a consensus development panel at its Bethesda, Maryland campus to develop guidelines on liver transplantations. This was stimulated in part by such recent clinical advances as the utilization of cyclosporine and widespread publicity on the feasibility of organ transplants. The NIH panel was specifically charged with determining what kinds of patients would benefit from liver transplantations; evaluating the skills, resources, and institutional support necessary to perform the procedure; and outlining avenues for further research. Under the direction of Doctor Rudi Schmid of the University of California at San Francisco, thirteen experts from the United States met for three days to review the current literature, hear testimony, and develop recommendations on the feasibility of liver transplantation. The summary report of the NIH panel appears elsewhere in this *Journal*.

I was privileged to serve as a member of the panel, and what follows is a personal assessment of our deliberations.

The Feasibility of Liver Transplantation

The first human orthotopic liver transplantation was performed at the University of Colorado in 1963. In the past 20 years, more than 540 such procedures have been performed in the United States and Western Europe, including some 70 in children. Because of the successful use of cyclosporine as an immunopharmacologic agent,

more institutions soon are expected to initiate the procedure. Public interest was heightened as the result of the heart transplant performed at the University of Utah in late 1982 and because of several widely-publicized cases involving liver dysfunctions in children. Liver transplantations appeared to benefit some patients; yet the procedure was still regarded as "experimental" by many physicians and insurance carriers.

After an exhaustive review, the NIH consensus development panel concluded that, in the words of our final report, the available evidence "clearly demonstrates that liver transplantation offers an alternative therapeutic approach which may prolong life in some patients suffering from severe liver disease that has progressed beyond the reach of currently available treatment and consequently carries a poor prognosis." While the clinical considerations behind this cautious statement are significant, its fiscal ramifications are even more apparent. An estimated 5,000 patients annually would benefit from a transplantation procedure, if suitable organs were available, at an approximate cost of \$100,000 each.

Third-party payers have been subjected to demands by their subscribers to cover the procedure, and it is likely that these pressures will intensify as a result of the action of the NIH panel. The federal Health Care Financing Administration, for example, often relies on information from the National Institutes of Health to determine if it will pay for procedures under federal programs. In Rhode Island, the General Assembly last year approved legislation which authorizes payment for liver transplantations under the state's Catastrophic Health Insurance Program (CHIP). In response to consumer demands, Blue Cross & Blue Shield of Rhode Island recently offered an optional "transplant rider" under its plans for larger groups.

Because of the far-reaching implications of the

Charles E. Millard, MD, is a family physician in Bristol, Rhode Island, and past president of the Rhode Island Medical Society (1981-1982). He was one of three practicing physicians appointed to the 13-member National Institutes of Health Consensus Development Conference on Liver Transplantation which met in June 1983.

panel's findings, it would be worthwhile to report how the panel reviewed the available data, assessed the impact of cyclosporine, and outlined criteria for the selection of suitable candidates.

Recent Clinical Advances

While the panel analyzed clinical data from both Western Europe and the United States, it focused its attention on the experiences of the four US medical centers where liver transplantations were then performed: the University of California at Davis; University of Minnesota Medical School at Minneapolis; University of Pittsburgh School of Medicine; and University of Tennessee College of Medicine at Memphis. Doctor Thomas E. Starzl from the University of Pittsburgh served on the panel, and the panel reviewed written documentation and oral presentations by representatives of the three other centers.

It was quickly discovered that the information necessary for a truly comprehensive evaluation of liver transplantations is not yet available. Briefly summarized, the existing data reveal favorable results with certain groups of patients. Many of those who are considered as potential transplant recipients face imminent death without the procedure. While many patients have survived with a comparatively healthy existence for years after transplantation, the procedure does present a considerable number of clinical problems. Among these are massive hemorrhage, renal dysfunction, graft rejection, biliary tract complications, graft vascular obstruction, and infection. Although the survival rate at one month ranges between 20 and 40 per cent, the one-year survival rate has increased significantly during the past decade. Moreover, the incidence of the other complications recently has declined because of the use of cyclosporine and the recent introduction of the intraoperative veno-venous caval bypass.

The immunosuppressive qualities of cyclosporine, a comparatively newly-discovered derivative of a fungus from Norway, were first noted in 1972. Since 1978, numerous clinical trials have demonstrated that cyclosporine is as good as or significantly better than the hitherto standard azathioprine-prednisone therapy for most organ transplantation procedures. Transplant patients who receive cyclosporine generally retain their grafts longer and have fewer rejection episodes than patients treated with conventional agents. Cyclosporine primarily affects lymphocytes. While concurrent prednisone therapy is required to help patients repress macrophage-

Table 1. Alcoholic Liver Disease

1. Transplantation reserved for patients who have been verified to stop drinking for at least six months
2. Adverse prognostic factors which may imply the need for transplantation:
 - Spontaneous encephalopathy
 - Hepatorenal syndrome
 - Prolonged prothrombin time (4 seconds)
 - Serum bilirubin more than 20 mg/dL
 - Progressive course despite therapy
3. Transplant experience with 25 patients show 20 per cent one and three-year survival with no apparent recent improvement

Conclusion: Not many ideal candidates; candidates probably identifiable; candidates often acutely ill resulting in logistical difficulties; transplant experience small and results poor; and further studies of alternate therapy needed.

mediated immunity, the necessary doses are much lower. As a result, patients suffer from fewer of the adverse effects of corticosteroid therapy

The use of cyclosporine is not without problems, however, and its potential adverse effects include nephrotoxicity, hepatotoxicity, hirsutism, tremors, hypertension, hemolytic anemia, thrombocytopenia, lymphoma, and lymphoproliferative disease. The incidence of lymphomas, for example, appears to be significantly higher with cyclosporine although clinical investigators note that it is difficult to attribute the etiology of malignant neoplasms to this agent. Many transplant recipients also receive prednisone in their treatment regimens. Researchers also point out that many of the "lymphomas" actually later turn out to be a form of lymphoproliferative disease which regresses when the immunosuppressive therapy is discontinued. Many of the other adverse effects also are reduced with lower doses of cyclosporine. The most frequent neoplasms observed in transplantation patients are cancers of the skin and lip and non-Hodgkin lymphomas, especially reticulum cell sarcomas.

The panel was especially impressed by the results with cyclosporine in cadaveric renal transplantation. In one European clinical trial performed in eight centers with 232 patients, 73 per cent of 117 kidney transplant patients who received a combination of cyclosporine and methylprednisone still retained their grafts after one year, compared to 53 per cent of 115 patients given azathioprine and prednisone. A Canadian trial yielded similar results, although clinical trials conducted in the United States have been less conclusive. Both the University of Pittsburgh and

the University of Texas at Houston found cyclosporine to be superior, although the University of Minnesota determined that patients treated with cyclosporine and those given conventional therapy have similar rejection rates. Doctor Starzl, speaking of the Pittsburgh experience with cyclosporine, told the panel: "One-year graft survival after familial transplantation in good centers has been so high that statistically significant increases with a new form of immunosuppression would be difficult to achieve."

Addressing the issue of liver transplantation, Doctor Starzl also told the panel that the one-year survival rate at the University of Pittsburgh now exceeds 50 per cent as the result of cyclosporine usage. Since 1981, the drug has been used in conjunction with more than 135 transplantation procedures at that institution. Because the liver is the major site of cyclosporine metabolism, Doctor Starzl pointed out that the transplantation team initially was concerned that an overdose might occur in patients with malfunctioning grafts. The opposite has occurred, he said, "in that unreliable gastric absorption of the drug has been the most consistent problem, with consequent underdosage."

Suitable Candidates for Transplantation

The selection of suitable candidates for the transplantation procedure was another issue that stimulated considerable discussion among the panel. The American Liver Foundation estimates that one million hospital admissions and 50,000 deaths in 1983 are attributable to liver disease. It has been estimated that only 5,000 of these patients would be suitable candidates for the procedure. After a thorough review of the literature and oral testimony by experts in the field, the panel determined which patients would be most likely to have a satisfactory result from transplantation. It also evaluated other methods of

therapy and examined the survival rates of patients who had received more conventional forms of treatment. Specific criteria sets were developed for each of the disease entities under discussion.

The panel concluded that patients most likely to benefit from liver transplantation procedures are those with biliary atresia, chronic active hepatitis, and primary biliary cirrhosis. Other less common potential candidates include patients with alpha-antitrypsin deficiency, Wilson's disease, Criglar-Najjar syndrome, and some genetic disorders.

The criteria set for alcoholic liver disease is outlined in Table 1. While the table illustrates the kinds of issues which the panel examined for each liver dysfunction, I should like to discuss it further because of the prognostic and ethical problems involved. Cirrhosis and alcohol-related hepatitis are the most prevalent forms of mortal liver disease in the United States. Although potential transplantation candidates should satisfy the criteria enumerated in Table 1, the panel felt that only a very small proportion of these patients would for several reasons benefit from the procedure. First, it must be verified that the patient has ceased drinking for at least six months and is likely to continue abstinence. Second, of the potential candidates who have satisfied this condition, it is likely that those with the stated indications of progressive disease are more acutely ill than other potential recipients. Their unstable condition could create problems with carrying out the transplantation procedure which would not otherwise exist. The experience data reveal that of 25 transplantation patients with alcoholic liver disease, only ten have survived at least three years and none have demonstrated any significant recent improvements. For these reasons, we strongly recommend that other treatment approaches for this disease be evaluated.

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SPECIAL REPORT

National Institutes of Health Consensus Development Conference: Liver Transplantation

The National Institutes of Health on June 20-23, 1983 convened a Consensus Development Conference on Liver Transplantation. Members of the Consensus Development Panel were: Rudi Schmid, MD (panel chairman), San Francisco; Donald M. Berwick, MD, Boston; Burton Combes, MD, Dallas; Ralph B. D'Agostino, PhD, Boston; Stuart H. Danovitch, MD, Washington, DC; Harold J. Fallon, MD, Richmond, VA; Olga Jonasson, MD, Chicago; Charles E. Millard, MD, Bristol, RI; Linda Miller, MS, Washington, DC; Frank G. Moody, MD, Houston; William K. Schubert, MD, Cincinnati; Laurence Shandler, MD, Santa Fe, NM; Henry J. Winn, PhD, Boston. After two days of expert presentation of the available data, the panel consisting of hepatologists, surgeons, internists, pediatricians, immunologists, biostatisticians, ethicists, and public representatives considered the offered evidence to arrive at answers to the following key questions:

1. Are there groups of patients for whom transplantation of the liver should be considered appropriate therapy?
2. What is the outcome (current survival rates and complications) in different groups?
3. In a potential candidate for transplantation, what are the principles guiding selection of the appropriate time for surgery?
4. What are the skills, resources, and institutional support needed for liver transplantation?
5. What are the directions for future research?

Liver Transplantation

Liver transplantation is a promising alternative to current therapy in the management of the late

From a report prepared by the Office for Medical Application of Research, National Institutes of Health, Bethesda, Maryland. The conference was sponsored by the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, and the Office for Medical Application of Research. Charles E. Millard, MD, Bristol, Rhode Island, served as a panel member.

phase of several forms of serious liver diseases. Candidates include children and adults suffering from irreversible liver injury who have exhausted alternative medical and surgical treatments and are approaching the terminal phase of their illness. In many forms of liver disease, the precise indications and timing of liver transplantation remain uncertain or controversial.

Prolongation of life of good quality for patients who would otherwise have died has been reported in the following conditions:

Extrahepatic biliary atresia is the most common cause of bile duct obstruction in the young infant. Patients who fail to respond to hepatoporoenterostomy (Kasai procedure) often benefit from liver transplantation. Recent data suggest that as many as two thirds of these patients survive for one year or more after transplantation.

Chronic active hepatitis is caused by viral infections or drug reactions, but many cases remain unexplained. Some patients with progressive liver failure are candidates for transplantation. Currently, exceptions seem to include drug-induced chronic active hepatitis, which usually responds to removal of the chemical agent, and hepatitis B-induced disease in which viremia persists. In the latter instance, rapid reappearance of infection with progressive liver failure has been reported after transplantation.

Primary biliary cirrhosis is a slowly progressive cholestatic liver disease. Results of transplantation appear favorable for patients with end-stage liver injury. The procedure may improve the quality of life.

Inborn errors of metabolism may cause end-stage liver damage or irreversible extrahepatic complications. Transplantation may be appropriate for such patients.

Hepatic vein thrombosis (Budd-Chiari syndrome) often results in progressive liver failure, ascites, and death. Patients who have not responded to anticoagulation or appropriate surgery for portal decompression may be candidates for transplantation.

Sclerosing cholangitis, a chronic nonsuppurative inflammatory process of the bile ducts, may cause liver failure. Less favorable results after transplantation in this group may be caused by prior multiple surgical procedures, a diseased extrahepatic bile duct, the presence of biliary infection, or other factors.

Primary hepatic malignant neoplasms confined to the liver but not amenable to resection may be an indication for transplantation. Results to date indicate a strong likelihood of recurrence of the malignant neoplasm. Nevertheless, the procedure may achieve substantial palliation.

Alcohol-related liver cirrhosis and alcoholic hepatitis are the most common forms of fatal liver disease in America. Patients who are judged likely to abstain from alcohol and who have established clinical indicators of fatal outcome may be candidates for transplantation. Only a small proportion of alcoholic patients with liver disease would be expected to meet these rigorous criteria.

Although *fulminant hepatic failure* with massive hepatocellular necrosis induced by hepatitis viruses, hepatotoxins, or certain drugs may warrant liver transplantation, rapid progression of the disease and multiorgan system failure frequently preclude this option.

Current Survival Rates and Complications

The survival and complication rates of patients who have undergone liver transplantation are the major criteria for judging efficacy. Data are available from four locations. The interpretation of the existing data on survival is extremely difficult because no control data are given for comparison, surgical techniques, and drug therapies varied over time. Moreover, patient selection criteria and management differed among centers.

While sufficient data for thorough assessment of liver transplantation are not available to date, certain trends appear to emerge. Patients currently being accepted for transplantation have a high probability of imminent death and a low quality of life in the absence of transplantation. Patients undergoing transplantation have an operative mortality (within one month) of 20 to 40 per cent. One-year survival among transplant recipients since 1980 is favorable when compared with their expected course in the absence of transplantation. Since 1980, one-year survival appears improved over the earlier transplant experience. Individual patients have survived for many years with good quality of life after transplantation. Data are insufficient to evaluate sur-

vival rates beyond one year after transplantation with current technologies. Short-term quality of life is probably enhanced in many transplant survivors. We lack systematically gathered information on quality of life among long-term survivors.

Severe nonlethal complications of transplantation frequently occur and must be taken into account in judging efficacy of this procedure. Massive hemorrhage is the most serious intraoperative and early postoperative problem. Other postoperative complications include renal dysfunction, rejection, biliary tract complications, graft vascular obstruction, and infection. With accumulating expertise in medical and surgical management and with new developments in technology (eg, intraoperative veno-venous bypass and cyclosporine), these complications can be expected to diminish.

Appropriate Time for Surgery

Selecting an appropriate stage for a given illness for liver transplantation is a complex issue: transplantation just before death may substantially diminish the lifesaving potential of the procedure, since hepatic decompensation in its latest stages poses a formidable surgical risk. Transplantation early in the course of hepatic decompensation may deprive a patient of an additional period of useful life.

An ideally timed liver transplantation procedure would be in a late enough phase of disease to offer the patient all opportunity for spontaneous stabilization or recovery, but in an early enough phase to give the surgical procedure a fair chance of success. For most patients, these phases are difficult to define prospectively. While no single best time for surgery can be specified, transplantation should be reserved for patients in any of the following phases of disease: when death is imminent; when irreversible damage to the central nervous system is inevitable, or when quality of life has deteriorated to unacceptable levels.

The exact choice of the time for liver transplantation in a person requires the judgment of a qualified medical team and a well-informed patient. The following are offered as guidelines for individual liver diseases:

Extrahepatic Biliary Atresia: Biliary enteric anastomosis (hepatportoenterostomy of Kasai) performed in the first two months of life provides substantial improvement for at least five years in one third of the patients, although cirrhosis and disappearance of the intrahepatic bile ducts occur with increasing age. While success of this procedure cannot be predicted for the individual

patient, it should be used as initial therapy for extrahepatic biliary atresia. In the absence of severe hepatic decompensation in these children, liver transplantation should be delayed as long as possible to permit the child to achieve maximum growth. In children with successful hepatoporoenterostomy, liver transplantation should be deferred until progressive cholestasis, hepatocellular decompensation, or severe portal hypertension supervene.

Chronic Active Hepatitis: The potential for spontaneous remission and the complex course of chronic active hepatitis make valid predictions of the subsequent course difficult except in the latest stages of the disease. Using strict criteria, patients can be recognized who have almost no chance of survival beyond six months. Such patients may be suitable candidates for transplantation.

Primary Biliary Cirrhosis: The indolent course of primary biliary cirrhosis and the potential for spontaneous improvement even in patients with advanced disease make transplantation potentially suitable only in the final stages of liver failure or when the quality of life has deteriorated to an unacceptable level.

α_1 -Antitrypsin Deficiency: Of the some 20 phenotypes in this genetic disorder, only Pi ZZ is associated with substantial hepatic disease in children. Jaundice usually is transient, clearing before 6 months of age, although biochemical evidence of activity may persist. Liver transplantation is indicated in children with Pi ZZ phenotype only when cirrhosis has developed and when evidence of hepatic failure is present.

Adults with α_1 -antitrypsin deficiency may have liver disease associated with phenotype Pi ZZ, MZ, or SZ. If hepatic failure occurs, liver transplantation may be indicated.

Wilson's Disease: Patients with Wilson's disease usually are responsive to chelation therapy with penicillamine. However, some patients are initially seen with fulminant hepatic failure, progressive disease, or both who are unresponsive to adequate chelation therapy. Liver transplantation may be indicated in these instances.

Crigler-Najjar Syndrome: Of the two types of this genetic disorder associated with severe unconjugated hyperbilirubinemia, patients with type I invariably experience bilirubin encephalopathy usually before 15 months of age. Because of the inevitability of CNS damage and the limitations of phototherapy, liver transplantation is indicated in such patients at an early age.

Miscellaneous Metabolic Diseases: A number of

rare genetic diseases may involve the liver and cause cirrhosis and eventual hepatic failure. Patients with tyrosinemia, Byler's disease, Wolman's disease, and glycogen storage diseases types 0 and IV may be candidates for hepatic transplantation. Liver transplantation may also be indicated for patients with certain genetic diseases associated with severe neurological complications, such as hereditary deficiency of urea cycle enzymes and disorders of lactate-pyruvate or amino acid metabolism.

Hepatic Vein Thrombosis: The course of hepatic vein thrombosis is variable, and, therefore, transplantation should be reserved for patients with severe hepatic decompensation. The possibility of later transplant surgery should not discourage the use of portal venous decompression when otherwise indicated.

Primary Sclerosing Cholangitis: No clinical, biochemical, serological, or histological factors have proved to be of value in predicting outcome. When appropriate attempts at biliary tract diversion and dilatation have failed, and death from liver failure is imminent, liver transplantation should be considered.

Alcoholic Liver Disease: At least 50 per cent of the cases of cirrhosis in the United States are attributable to the abuse of alcohol, and alcohol abuse is the leading cause of hepatic morbidity and mortality. Alcohol liver disease is most favorably affected by abstinence. The natural history of untreated alcoholic hepatitis, cirrhosis, or both is extremely variable, and there are few precise prognostic indicators in any but the terminal phase of the disease.

Liver transplantation may be considered for the patients in whom evidence of progressive liver failure develops despite medical treatment and abstinence from alcohol.

Institutional Support Needed for Liver Transplantation

The requirements for conducting a liver transplantation program by a sponsoring institution are formidable. Accordingly, any institution embarking on this program must make a major commitment to its support. In addition to the full array of services required of a tertiary care facility and a program in graduate medical education, an active organ transplantation program should exist. Few hospitals are likely to meet these prerequisites.

Liver transplant recipients are seriously ill before surgery. The transplant effort is prodigious, and the postoperative intensive care interval,

averaging two weeks, is punctuated by complications and frequent need for reoperation.

In this context, experts in hepatology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, and anesthesiology are needed to complement a qualified transplantation team. Extensive blood bank support to provide the needed copious quantities of blood components is mandatory. Similarly, sophisticated microbiology, clinical chemistry, and radiology assistance are required. Emotional support for patient and family warrants psychiatric participation. Availability of effective social services to assist patients and families is indispensable.

The transplantation surgeon must be trained specifically for liver grafting and must assemble and train a team to function whenever a donor organ is available. Institutional commitment to the program mandates that operating room, recovery room, laboratory, and blood bank support exist at all times. Allocation of intensive care and general surgical beds is important. Recruitment of a cohort of specialized nurses and technicians to staff these areas is necessary. Access to tissue-typing capability; ongoing research programs in liver disease, organ preservation, and transplantation immunology; and available hemoperfusion and microsurgical techniques are desirable attributes of a transplantation effort.

Participation in a donor procurement program and network is essential, and an interdisciplinary deliberative body should exist to determine on an equitable basis the suitability of candidates for transplantation.

Institutions conducting liver transplantation are obligated to prospectively collect and share data in a coordinated, systematic, and comprehensive manner in all patients selected as transplantation candidates, so that the role of liver transplantation in the treatment of patients with liver disease can be assessed properly. Additional information permitting cost-benefit analysis should be secured.

Directions for Future Research

The Consensus Panel identified several broad areas related to liver transplantation in which critically important information is either unavailable or so incomplete as to defy meaningful interpretation. It is recommended that a registry or clearinghouse be established for collection and

evaluation of all available data on liver transplantation. Such a center would develop unified criteria for selection of patients for transplantation and for reporting and evaluating all data related to the outcome of the operation and the patient's postoperative and long-term condition. As methods of immunosuppression improve and the logistic obstacles are resolved, the feasibility and desirability of randomized clinical trials of liver transplantation should be explored for suitable subgroups of patients with specific liver diseases.

High priority also should be given to research projects related to several aspects of the transplant procedure itself. Means should be developed to improve preservation of human liver *ex vivo*, and criteria should be established to evaluate its viability. Improved control of organ rejection requires urgent attention; this includes thorough evaluation of the benefits and risks of cyclosporine as an immunosuppressive agent in liver transplantation. The design of the hemodynamic support system during transplantation needs evaluation and potential improvement. Research should be encouraged for developing better supportive measures for patients with liver failure, including maintenance of proper renal and cerebral function.

In the broad areas of the cause, pathogenesis, and natural course of chronic liver disease, present knowledge is fragmentary and incomplete, and research in these areas should be fostered and supported by all available means. Particular attempts should be made to determine the possible role of liver transplantation in the management of hepatocellular carcinoma at a stage when metastatic spread appears remote. Similarly, approaches should be sought to limit infection of the transplanted liver by hepatotropic viruses.

Conclusion

After extensive review and consideration of all available data, this panel concludes that liver transplantation is a therapeutic modality for end-stage liver disease that deserves broader application. However, for liver transplantation to gain its full therapeutic potential, the indications for and results of the procedure must be the object of comprehensive, coordinated, and ongoing evaluation in the years ahead. This can best be achieved by expansion of this technology to a limited number of centers where performance of liver transplantation can be carried out under optimal conditions.

Corneal Transplantation: Current Concepts and Practices

*The Success Rates for the Operation Are Nearly as High as
for Cataract Surgery*

Paul S. Koch, MD

The dream of replacing diseased body parts with healthy donated organs was realized shortly after the turn of the century when both corneas in a young Austrian boy were replaced with donated corneas. One transplant failed almost immediately after the operation, but the other remained clear for many years.

Since that time corneal transplantation, also called corneal grafting or penetrating keratoplasty, has become the most widely performed and successful transplantation operation. More than 120,000 procedures have been performed to date, and it is estimated that 10,000 corneal transplantations are performed in the United States each year.¹ Even without screening the donor tissue for compatibility, the likelihood of attaining a clear graft in properly selected patients is 90 per cent.

Many patients who could benefit from corneal transplantation unfortunately are not advised of the availability of the operation. The procedure is almost as successful as cataract surgery (90 per cent versus 95 per cent) and is performed in the same manner using the operating microscope under general or local anesthesia.² The discomfort following corneal surgery is no greater than after cataract surgery and much less than after strabismus surgery. Eyedrops must be used for longer periods after a corneal transplantation than after other forms of eye surgery. All patients with opaque corneas should be advised to seek

consultations from surgeons experienced in corneal transplantations. From my own practice experience, I would estimate that more than 200 Rhode Islanders are unaware that they might benefit from the procedure.

The cornea is a transparent dome in the front of the eye which is responsible for 80 per cent of the refractive or optical power of the eye. The major portion of its thickness consists of the stroma, which is made up of collagen lamellae oriented for optical clarity. Because the cornea does not have blood vessels, it receives its oxygen supply from the oxygen content of the internal aqueous humor and the external tear film. The low level of metabolism facilitates the removal of donor corneal tissue and its transportation and storage before transplantation surgery. Also, most circulating antibodies are isolated from the cornea, resulting in few significant cases of graft rejection, although mild rejection reactions are common. Corneas which have become vascularized because of scarring tend to have more serious rejection reactions.

Mild treatable graft rejection reactions occur in approximately 12 per cent of cases.³ While steroid eyedrops usually are sufficient to eliminate the reaction, some patients require systemic steroids, subconjunctival injections of steroids, or both. Immune allograft reactions are caused by specific antigens in the donor cornea which are presumed to be the histocompatibility antigens (HLA) similar to those responsible for graft rejections in other transplantation procedures. It is not entirely clear that these are the only antigens or even the most significant ones.⁴ Because clear grafts in favorable cases are attained 90 per cent of the time, HLA matching is not performed routinely except in patients with heavily vascularized corneas. The incidence of significant graft rejection without tissue typing can be greater than 25 per cent in these cases.³

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Graft Procurement

The lack of an adequate number of donor corneas remains a problem. In Rhode Island, corneas are not obtained routinely after death except at the request of the family. After a call for instructions to the New England Eye Bank in Boston, a local ophthalmologist usually is sought to enucleate the eyes. As a result of such delays, the corneas from many potential donors may become unsuitable for transplantation. While in some cases the enucleation procedure may be performed up to 24 hours after death, corneas suitable for transplantation usually have to be obtained within six hours.

Other states, such as Florida, require that the corneas of all medical examiner cases, ie, sudden deaths, suspicious deaths, or deaths within 24 hours of hospital admission, be removed unless the family objects. As a result, there are areas of the United States with far more donor tissue available than can be used. Another benefit of such laws is that the average age of the donors frequently is much lower than in areas where corneas are obtained only by family request.

Enucleations, or removal of the eyes, can be performed with a handful of instruments in only a few minutes by trained persons who need not be physicians. When I was employed by the Eye Bank for Sight Restoration in New York City, enucleators included a high school biology teacher, a mortician, and an operating room technician. I performed enucleations in morgues, funeral parlors, hospital beds, patients' homes, and, in one instance, in a bathroom while policemen hovered over me conducting an investigation. In contrast, as an intern in Providence, I was once denied permission to obtain donated eyes because the hospital administration was reluctant to call in an operating team, despite my insistence that that would not be necessary. The medical community should be educated as to the technical ease of obtaining eyes so that additional suitable corneas may be available for transplantation.

Methods

Most eyes are suitable for transplantation, either for a penetrating keratoplasty (the usual corneal transplant), for a lamellar (partial thickness) keratoplasty, or for such refractive corneal operations as keratophakia, hemoplastic keratomileusis, or epikeratophakia. Since poor vision is usually due to cataracts or circulatory problems rather than to corneal disease, the eyesight prior to death is not a factor. Age is a consideration, however, because younger corneas are healthier



Fig 1. Case 1: Preoperative appearance of right eye with a scarred cornea due to herpes simplex keratitis. Visual acuity 20/400.

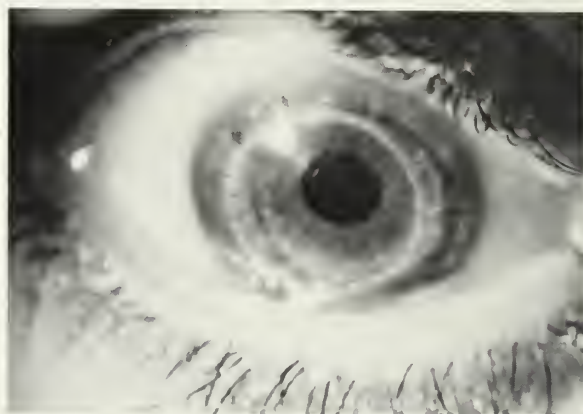


Fig 2. Case 1: Postoperative appearance of the corneal transplant. Interrupted sutures for astigmatism control are visible. Visual acuity 20/20.

and better suited for penetrating keratoplasty, although older corneas, when properly handled, can be fully as satisfactory. The age of the donor becomes inconsequential if the thickness of the cornea and the concentration of endothelial cells are adequate.

Conditions which cause a cornea to be rejected include delayed harvesting following death, excessive edema, inadequate endothelium, evidence of excessive trauma in the recovery of the eyes, and certain causes of death including hepatitis, syphilis, slow virus diseases, and acute forms of leukemia.¹ The death of a patient who contracted rabies from a donated cornea was recently reported.

The enucleated eyes from donors having suitable medical histories are examined under high magnification. If a cornea appears adequate for transplantation, it is cultured and irrigated with antibiotics. The cornea is removed with a thin rim of sclera and is placed in a sterile tissue culture

solution. This allows the cornea to be preserved for up to five days while a suitable recipient, often in another part of the country, is located. Even though the cornea is preserved, time is important and the surgery should be performed as quickly as possible.

The operation may be carried out under either general or local anesthesia. A round trephine is used to excise a portion of the central cornea from the recipient. The periphery is spared whenever possible to reduce the likelihood of a vascular reaction and subsequent corneal rejection. A slightly larger trephine is used to punch out a round button from the donor cornea. The donor cornea is sutured under microscopic control into the recipient bed with a fine non-absorbable suture.² Following the operation, steroid eyedrops are applied daily for several weeks. Vision usually begins to recover in a few days. While it generally reaches a functional level in about a month, an occasional fortunate patient can see quite well after only one or two days.

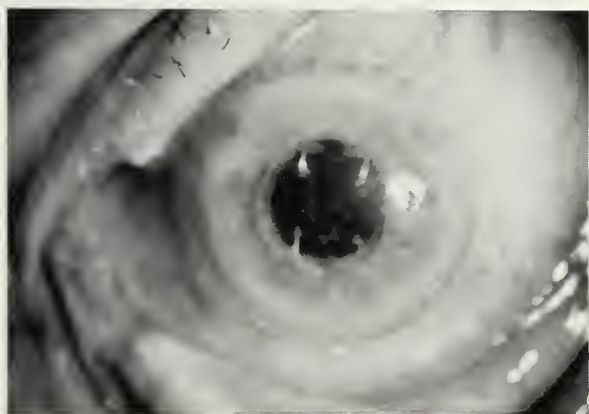


Fig 3. Case 2: Preoperative appearance of a cloudy cornea with pseudophakic bullous keratopathy. Visual acuity limited to light perception.



Fig 4. Case 2: Postoperative appearance of the corneal transplant. Visual acuity improved to 20/30.

Formerly, a corneal transplant was considered to be successful if it was clear and retained its clarity over a period of time. Now a transplant must not only be clear, but also provide adequate vision for the patient. The graft must, as far as possible, be free from astigmatism. Astigmatism is an irregularity of the corneal surface which results in one meridian having a different curvature from another, with the cornea shaped like a football rather than a basketball.⁶ A cornea with pronounced astigmatism cannot be considered a successful transplant. The intraoperative use of a surgical keratometer allows the surgeon to adjust the astigmatism of the cornea at the time of transplantation, or at a later time if a graft revision proves necessary.⁶⁻⁹

Graft revisions are usually accomplished by resection of a corneal wedge from the flat meridian of the transplant or a relaxing incision placed to increase the steepness of the flatter meridian.^{6, 10, 11} The Ruiz modification of radial keratotomy is especially useful for this purpose.¹³

Other Forms of Corneal Transplants

Corneal transplants for the repair of superficial corneal disease may be performed by lamellar keratoplasty. In this operation, the anterior half of the cornea is dissected and replaced with a similarly prepared piece of donor tissue. It presents fewer complications than penetrating keratoplasty because it is extraocular and does not distort the normal anatomy of the eye.⁶

Lamellar refractive keratoplasty is the collective name for a group of procedures designed to change the refractive, or optical, state of the eye. One such operation, keratophakia, utilizes only the stroma from a donor cornea which is frozen and carved on a lathe until it is shaped like a lens. It is then implanted within the midstroma of a



Fig 5. Case 3: Myopic keratomileusis prior to suture removal three weeks following the operation.

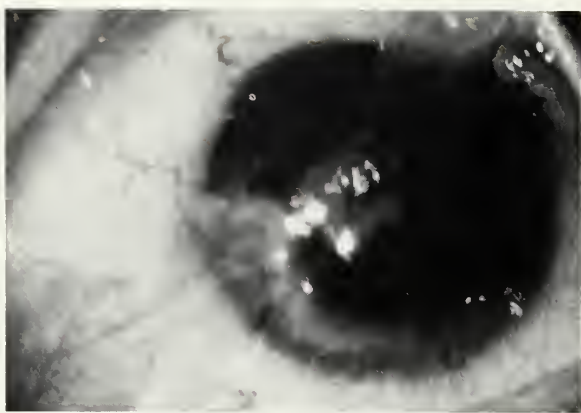


Fig 6. Case 4: Preoperative appearance of the nasal and temporal pterygia. Visual acuity 20/100.

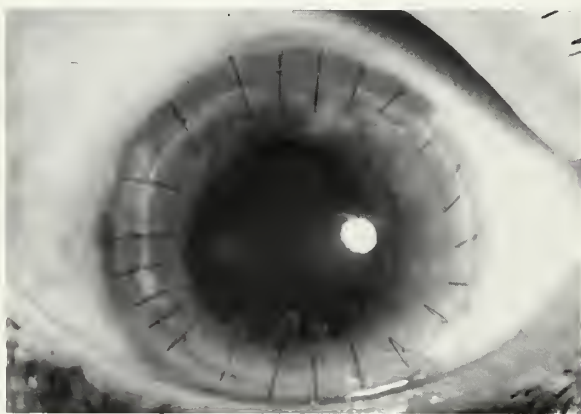


Fig 7. Case 4: Postoperative appearance after lamellar keratoplasty. Visual acuity is 20/30.

recipient cornea, providing the patient with the additional power of the carved corneal lens. Keratophakia may be used as an alternative to intraocular lens implantation following cataract surgery.¹²⁻¹⁶

Homoplastic keratomileusis utilizes a donor cornea which is frozen and reshaped to add or subtract a specified power, thereby reducing myopia (nearsightedness) or hyperopia (farsightedness).¹²⁻¹⁵ Myopic keratomileusis and radial keratotomy are the two most common ocular procedures now performed for the reduction or elimination of myopia.¹²

Case Histories

Case 1: A 15-year-old boy developed herpes simplex keratitis. Despite vigorous treatment with topical anti-herpetic medications, he developed a dense corneal scar and visual acuity fell from 20/20 to 20/400 (Fig 1). A corneal transplant was performed in September 1982 with tissue imported from Florida. Within 12 weeks, his vision

improved to 20/40. In addition to the running stitch, several interrupted sutures were placed to control astigmatism (Fig 2). The sutures have now been removed, there is virtually no astigmatism, and the vision is 20/25 without correction and 20/20 with correction.

Case 2: A cataract operation with an intraocular lens implantation was performed on a 70-year-old woman in 1980. Two years later the cornea developed bullous keratopathy and vision dropped to light perception (Fig 3). A corneal transplant was performed with retention of the intraocular lens. There is essentially no astigmatism, and the visual acuity is 20/50 without correction and 20/30 with correction (Fig 4).

Case 3: A 25-year-old male had unilateral high myopia (-16.0 diopters) and could not wear a contact lens. The uncorrected visual acuity was an ability to "count fingers" at eight inches in the myopic eye and 20/20 in the opposite eye. In May 1981, he became one of the first American pa-



Fig 8. Case 5: 10-month-old functionally-blind infant with bilateral opaque corneas due to congenital glaucoma.



Fig 9. Case 5: One year following operation. Functionally good vision. Photograph taken just prior to performing a corneal transplant on the opposite eye.

tients to be treated with myopic keratomileusis. Two weeks after surgery, the uncorrected vision was 20/100, and in two months it improved to 20/50, 20/30 with correction (Fig 5).

Case 4: A 65-year-old man had had nasal and temporal pterygia which grew to meet in the visual axis, causing his visual acuity to fall from 20/20 to 20/100 (Fig 6). He underwent excision of both pterygia with lamellar keratoplasty and his vision improved to 20/30 in 16 weeks (Fig 7).

Case 5: A 10-month-old infant was brought to this country from Central America with bilateral congenital glaucoma and opaque corneas. He was functionally blind. A trabeculotomy was performed on each eye with resultant control of the intraocular pressure, but the corneal opacities persisted (Fig 8). A corneal transplant was performed on the right eye in April 1981, and the child returned to Central America. When reexamined a year later, the transplant was clear (Fig 9). The infant seemed to have good vision and was able to follow moving objects. In February 1983, a corneal transplant was performed on the left eye, and the right eye was examined under anesthesia. It was found to be myopic (-7 diopters) and to have mild glaucomatous optic nerve damage ($C/D = 0.5$). It has been fitted with an

extended-wear contact lens to correct the myopia. No follow-up is available on the results of the operation on the left eye.

Conclusion

Corneal transplantation is a very delicate operation which can be performed by trained specialists in any hospital with equipment for ophthalmic microsurgery. Donor tissue is readily available where there are programs to solicit donations and scarce in areas where there is little or no interest in obtaining graft material. Many parts of the country, including Rhode Island, must import corneas from other states. Corneal transplantation is the most common and successful form of human organ transplantation. In addition to penetrating keratoplasty, there are also forms of lamellar keratoplasty designed for primary reconstruction and for refractive changes. Many patients, however, are discouraged from considering these procedures by well-meaning persons who are concerned that corneal transplantation is much riskier and more painful than it actually is. These patients should be advised to seek consultations from surgeons experienced in the field.

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Development of the Protocol for Organ Procurements at Rhode Island Hospital

Increasing Attention Is Given to Procurement and Transplantation of Kidneys, Livers, and Other Organs

Robert A. DeNoble, MBA

In January 1981, a young woman suffered a cerebral hemorrhage after giving birth, and was transferred to Rhode Island Hospital in Providence, Rhode Island. After learning that the patient exhibited signs of irreversible brain death, her family wanted to donate her organs for possible transplantation and called the New England Organ Bank. The donor bank is a Boston-based regional program established to facilitate the procurement and transplantation of organs. Representatives from the donor bank called the hospital to make the arrangement necessary to remove the young woman's kidneys for a later transplantation.

After this call and a review of the background facts of the case, we attempted to determine the hospital policies and procedures, if any, for dealing with such situations. No kidney procurement had been performed at Rhode Island Hospital since 1973, and there were no policies or procedures to provide guidelines for the immediate situation. After conferring with legal counsel, the medical staff, and the State Medical Examiners Office, hospital officials requested that the New England Organ Bank send a qualified team to procure the patient's kidneys.

The Executive Committee of the Medical Staff, anticipating the likelihood of similar situations in the future, appointed an ad hoc committee to examine the feasibility of kidney procurement by members of the Rhode Island Hospital medical staff. The ad hoc committee focused on three major issues. First, should the hospital participate in kidney procurements? Second, should physicians from the New England Organ Bank or from

the hospital staff perform the procedure? Third, if the hospital permitted physicians from the donor bank to perform these procedures, what relationship should exist between Rhode Island Hospital and the New England Organ Bank?

The Role of the Hospital in Kidney Procurement

As the first step in its deliberations, the ad hoc committee concluded that the procurement and transplantation of kidneys is a proven medical procedure which contributes substantially to the quality of life. With that premise as its basis, the committee then turned its attention to the legal ramifications of the procedure. The kidneys must be removed prior to the cessation of respiratory and circulatory functions, and the patient is maintained on a respirator until the procedure is completed. As a result, the primary legal issue faced by the committee was whether a declaration of death based on brain death criteria would protect those involved with the procedure.

The legal status regarding brain death criteria was reviewed by the legal counsel for the hospital. At the time, the State of Rhode Island lacked a statutory definition of brain death, and there were no guiding judicial determinations from the state courts. Consequently, the common law rule, eg, that death occurs upon the cessation of respiratory and circulatory functions, would prevail in the absence of a specific law or court ruling. The attorney, however, cited national trends over the past ten years which have shaped a definition of brain death. These consisted of legislative definitions approved by the legislatures of 26 states and court decisions in nine others, including a ruling by the Massachusetts Supreme Court. It was his opinion that the accumulated judicial precedent, especially the Massachusetts opinion, would influence the Rhode Island courts if they were confronted with the issue.

Robert A. DeNoble, MBA, is Vice-President, Rhode Island Hospital, Providence, Rhode Island. He received his MBA degree from Harvard Business School.

Since this analysis by the hospital legal counsel and the conclusion of the ad hoc committee's deliberations, a Uniform Determination of Death Act was enacted in Rhode Island. This act, passed during the January 1982 session of the General Assembly, provides that "an individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards." In August 1982, the Office of the State Medical Examiner promulgated rules and regulations to implement this legislation, and an analysis of these regulations has been published in an earlier issue of this *Journal*.¹

Because of its opinion that the procurement of kidneys contributes to the preservation of life and the existence of clear national legislative and judicial trends, the committee recommended that Rhode Island Hospital participate in a kidney procurement program.

Who Should Perform the Procedure?

The committee next focused on the development of an appropriate protocol. The chief of urology at the hospital reported that the urology staff had reviewed the legal status of the procedure, supported the procurement of kidneys, and would participate in such a program. He expressed concern, however, about the fact that each member of the urology staff probably would perform very few kidney procurements during the course of a year. It was felt that the number of operations done by each surgeon would not be sufficient to maintain the required expertise. As a result of this concern, the committee recommended that the procedure be performed on a regional basis by surgeons of the New England Organ Bank.

In 1983, however, the president of the New England Organ Bank visited Rhode Island Hospital, spoke to the ad hoc committee, and endorsed the concept of hospital urologists actively participating in the program. A group of eight urologists have agreed to share this responsibility and have declared themselves available. In most other New England hospitals, procurement is performed by local teams.

The Committee also dealt with the concerns of other professionals and support personnel on the hospital staff who would be involved. Because Rhode Island Hospital personnel are most familiar with the available facilities and equipment, the committee suggested that the operating room

staff from the hospital provide the support necessary for the procedure. This recommendation, after an opportunity for thorough discussion of the issues with the affected personnel, was endorsed by the operating room staff.

Relations with the New England Organ Bank

The ad hoc committee recommended that Rhode Island Hospital develop a formal relationship with the New England Organ Bank and adopt a protocol to cover the procedure. The committee further stipulated that, as part of the hospital's agreement with the donor bank, the hospital should be provided with the names and credentials of all donor bank surgeons who might perform such a procedure at the hospital. It also was recommended that the hospital president or his designee be permitted to grant temporary privileges for performing the operation to approved surgeons after a review of their credentials.

Program Implementation

The Executive Committee of the Medical Staff approved these recommendations in May 1981, as did the Board of Trustees later that year. In addition to a formal agreement with the New England Organ Bank, the hospital established a review mechanism to grant temporary privileges to surgeons from the donor bank. The Rhode Island Department of Health does not require these physicians to hold valid medical licenses in Rhode Island as long as a fully-licensed physician on the Rhode Island Hospital staff supervises operation of the program. This role is filled by the chief of urology.

After the overall policy was approved by the medical staff and governing body of the hospital, a formal protocol was developed. This protocol addresses the following considerations: the purpose of the protocol; the objectives of the program; general guidelines for identifying potential donors; responsibilities of referring physicians, the director of the operating room, nursing staff, and physicians from the New England Organ Bank and the transplant coordinator; billing procedures; and medical-legal deaths.

In accordance with the agreement between the hospital and the New England Organ Bank, twelve kidney procurement procedures have been performed at Rhode Island Hospital since January 1981.

Future Program Development

The major focus during the past several years has been on the procurement of kidneys. More and

more attention, however, is given to the procurement and transplantation of such other organs as livers, hearts, lungs, and bones. The ad hoc committee, originally established to examine the feasibility of kidney procurements, will broaden its focus and explore the possibilities and ramifications of an expanded organ procurement program. Indeed, orthopedic surgeons at Rhode Island Hospital already have performed a successful bone procurement procedure.

We look forward to further advances and developments in the area of organ procurement and transplantation so that we may contribute further to the quality of life in Rhode Island.

Reference

¹ Goldowsky SJ: Uniform determination of death. *Rhode Island Medical Journal* 66(8):309-311.

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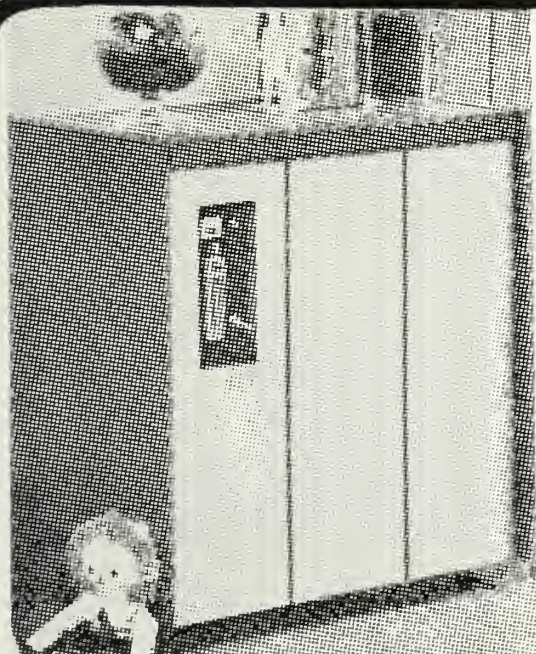
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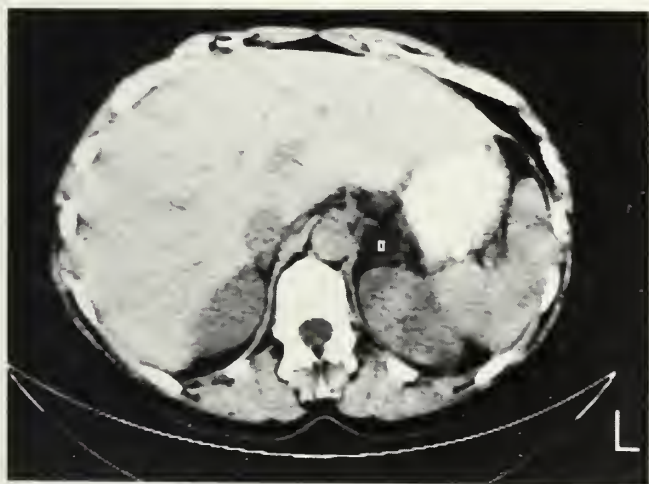


Fig 1. Non-contrast CT scan (5 mm thick) of the adrenal glands

Allan M. Deutsch, MD
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Howard R. Cohen, MD

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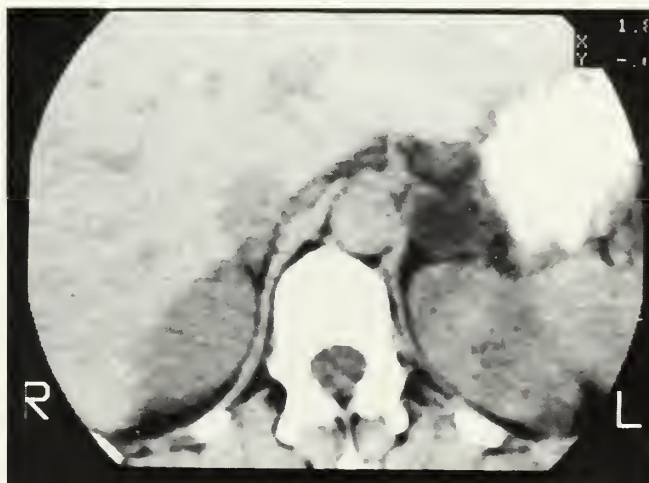


Fig 2. Photographic magnification of the adrenal glands

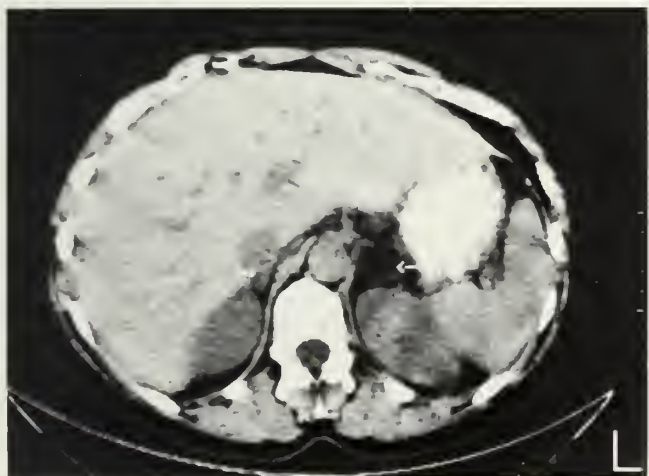


Fig 3. Range of interest measurement demonstrates an attenuation value of -25 Hounsfield units

History

40-year-old female with long-standing hypertension and complaints of muscle weakness.

For discussion turn to next page.

Radiographic Findings

A non-contrast scan of the adrenal glands demonstrates a mass of the left adrenal gland, 3 cm in diameter, showing an attenuation value within the range of fat tissue. The right adrenal gland is normal, as revealed by its posterior and medial concave borders.

Diagnosis

Aldosterone secreting adrenal tumor.

Discussion

The use of computed tomography (CT) in evaluating adrenal morphology is now a widely-accepted diagnostic modality. Until the advent of CT, such other diagnostic imaging methods as conventional radiography, scintigraphy, and ultrasound were used. Plain film radiography, combined with high-dose excretory urography and linear tomography, can detect masses only when they are greater than 2.5 cm in diameter.¹ While scintigraphy, using radionuclide iodinated cholesterol derivatives, can be used to localize cortisol or aldosterone-producing tumors, non-cortical tumors do not absorb the radiopharmaceutical agent. Furthermore, the examination requires several days to complete. Although gray-scale ultrasonography is often able to detect both normal and abnormal adrenal glands, the study is technically difficult to perform.

Computed tomography overcomes many of these disadvantages. With the development of rapid scanners and the ability to produce 5 mm thick sections, precise demonstration of normal adrenal glands and the detection of tumors smaller than 1 cm in diameter becomes feasible.² There is no delay before the procedure, and the study is not difficult from the standpoint of the operator.

On the axial images produced by CT, the adrenals are seen to be separated from the surrounding structures by retroperitoneal fat. The right adrenal gland is located just superior and anteromedial to the upper pole of the left kidney. The CT appearance of the normal adrenal gland usually falls into one of two major categories. The gland most commonly has the shape of an arrow-head or an inverted "V." If only one limb of the

inverted "V" is identified, the gland will appear as a linear or elongated density resembling a comma. More important than the shape of the gland is the fact that a normal adrenal gland always has straight or concave margins. The adrenal gland, regardless of intrinsic measurements, must be considered abnormal if the borders are externally convex.³

A specific pathologic diagnosis is rarely possible on the basis of the appearance of an adrenal lesion on CT examination. This is not essential, however, as the clinical presentation and the biochemical abnormalities of the patient are often distinctive. The CT permits the differentiation between bilateral hyperplasia and unilateral tumors.⁴

This patient presented with the clinical and biochemical manifestations of hyperaldosteronism. The autonomous hypersecretion of aldosterone may be caused by either hyperplasia or an adenoma of the adrenal cortex (about 75 per cent of cases).⁵ It is important to differentiate between the two etiologies since medical management is the treatment of choice in bilateral hyperplasia, while an aldosterone-producing tumor may be curable by an adrenalectomy.⁶

In addition to the evaluation of the adrenal gland for morphological manifestations of hyperplasia and primary tumors, computed tomography is an indicated modality for the evaluation of metastatic disease to the adrenals. The adrenal gland is a common site of metastases from bronchogenic carcinoma. Although this concept is more widely accepted for small cell carcinoma, recent studies have revealed that the adrenal gland is the most frequent site of metastases found at autopsies performed within one month of thoracic surgery.⁷ While prospective studies are not yet available, it appears reasonable to recommend CT evaluation of adrenal glands in patients with non-small cell lung cancer, as well as small cell, especially if they are undergoing CT examination of the chest.

It is apparent that computed tomography, when performed with rapid scanning techniques and thin (5 mm) sections, has become the initial diagnostic procedure of choice when evaluating the adrenal gland for cysts, hyperplasia, primary adrenal tumors, or metastatic disease.

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The National Heart, Lung, and Blood Institute recently published *Heart to Heart: A Manual on Nutrition Counseling for the Reduction of Cardiovascular Disease Risk Factors* (NIH Publication 83-1528). Designed primarily for health educators and nutrition counselors, the 120-page reference book includes information on nutritional assessment and monitoring techniques, nutrition counseling guidelines and skills, medical history and dietary habit worksheets, and a bibliography of additional resources. Single copies are available at no charge from the Public Inquiries and Reports Branch, Box HH, National Heart, Lung, and Blood Institute, Building 31-Room 4A21, Bethesda, MD 20205.

Infant walkers, under criticism for creating a high accident risk and producing abnormal gait patterns in normal children, also harm infants in the early stages of cerebral palsy. According to a paper in the December 1983 *American Journal of Diseases of Children*, researchers at the University of Washington, Seattle, report that the walkers exaggerate and perpetuate such primitive reflexes as "scissoring" of the legs and standing on the toes and may well lead to dislocation of the hips and contracture of the heel cords. The use of the walkers also delays development of balancing reactions and other protective responses.

While some automobile drivers require telescopic eye glasses to pass the driver examination and to read roadway signs, these lenses severely distort their view of the roadway. A report in the December 1983 *Archives of Ophthalmology* recommends that these drivers not be required to wear telescopic lenses, the so-called bioptic telescopic spectacles (BTS), as the telescopic part of the lens creates a large blind area in the peripheral field of vision. Moreover, the use of BTS lenses requires drivers either to reposition their heads or the glasses in order to read roadway signs. As the repositioning process takes an estimated three seconds, such a visually impaired driver traveling at 60 mph would have covered 264 feet by the time the entire process was completed. Many of these drivers, the report continues, compensate for their lack of visual acuity by becoming extremely familiar with their routes or taking passengers with them to read the road signs on unfamiliar roadways.

The first case of acquired immune deficiency syndrome (AIDS) reported in a homosexual male with hemophilia A is cited in the December 1983 issue of the *Archives of Internal Medicine*. Researchers at the Northwestern University Medical School, Chicago, report that their patients, as well as previously reported heterosexual male hemophiliacs with AIDS, had been treated with commercially-prepared factor VIII concentrate. Reduced helper-to-suppressor cell ratios, a hallmark of AIDS, have been found in 60 per cent of hemophilia A patients treated with factor VIII, which is obtained from plasma pools collected from up to 22,500 individual donors. None of the hemophiliacs treated with cryoprecipitate, a factor VIII fraction obtained from individual units of plasma only, demonstrated this finding. ■

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1. Stone PH, Turin ZG, Muller JE. Efficacy of nifedipine therapy for refractory angina pectoris. *Am Heart J* 104:672-681, September 1982
2. Antman E, Muller J, Goldberg S, et al. Nifedipine therapy for coronary artery spasm: Experience in 127 patients. *N Engl J Med* 302:1269-1273, June 5, 1980

BRIEF SUMMARY

PRDCARDIA (nifedipine) CAPSULES

For Oral Use

INDICATIONS AND USAGE: I. **Vasospastic Angina:** PRDCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation; 2) angina or coronary artery spasm provoked by ergonovine; or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PRDCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. **Chronic Stable Angina (Classical Effort-Associated Angina):** PRDCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PRDCARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PRDCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS

Known hypersensitivity reaction to PRDCARDIA.
WARNINGS: Excessive Hypotension. Although in most patients the hypotensive effect of PRDCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving PRDCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of PRDCARDIA and a beta blocker, but the possibility that it may occur with PRDCARDIA alone, with low doses of fentanyl, in other surgical procedures, or with other narcotic analgesics cannot be ruled out. In PRDCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PRDCARDIA to be washed out of the body prior to surgery.

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PRDCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PRDCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PRDCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PRDCARDIA.

Congestive Heart Failure: Rarely, patients, usually receiving a beta blocker, have developed heart failure after beginning PRDCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General: Hypotension. Because PRDCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PRDCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PRDCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug interactions: Beta-adrenergic blocking agents. (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PRDCARDIA and beta-blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long acting nitrates. PRDCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis. Administration of PRDCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PRDCARDIA to avoid possible over- or under digitalization.

Carcinogenesis, mutagenesis, impairment of fertility. When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy. Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients; transient hypotension in about 5%, palpitation in about 2% and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PRDCARDIA or concomitant antianalgesic medication. Additionally the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PRDCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PRDCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PRDCARDIA therapy, has been reported twice in the extensive world literature.

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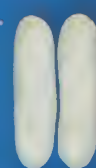
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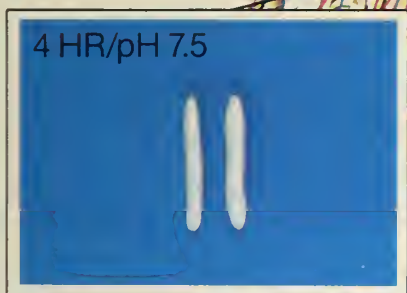
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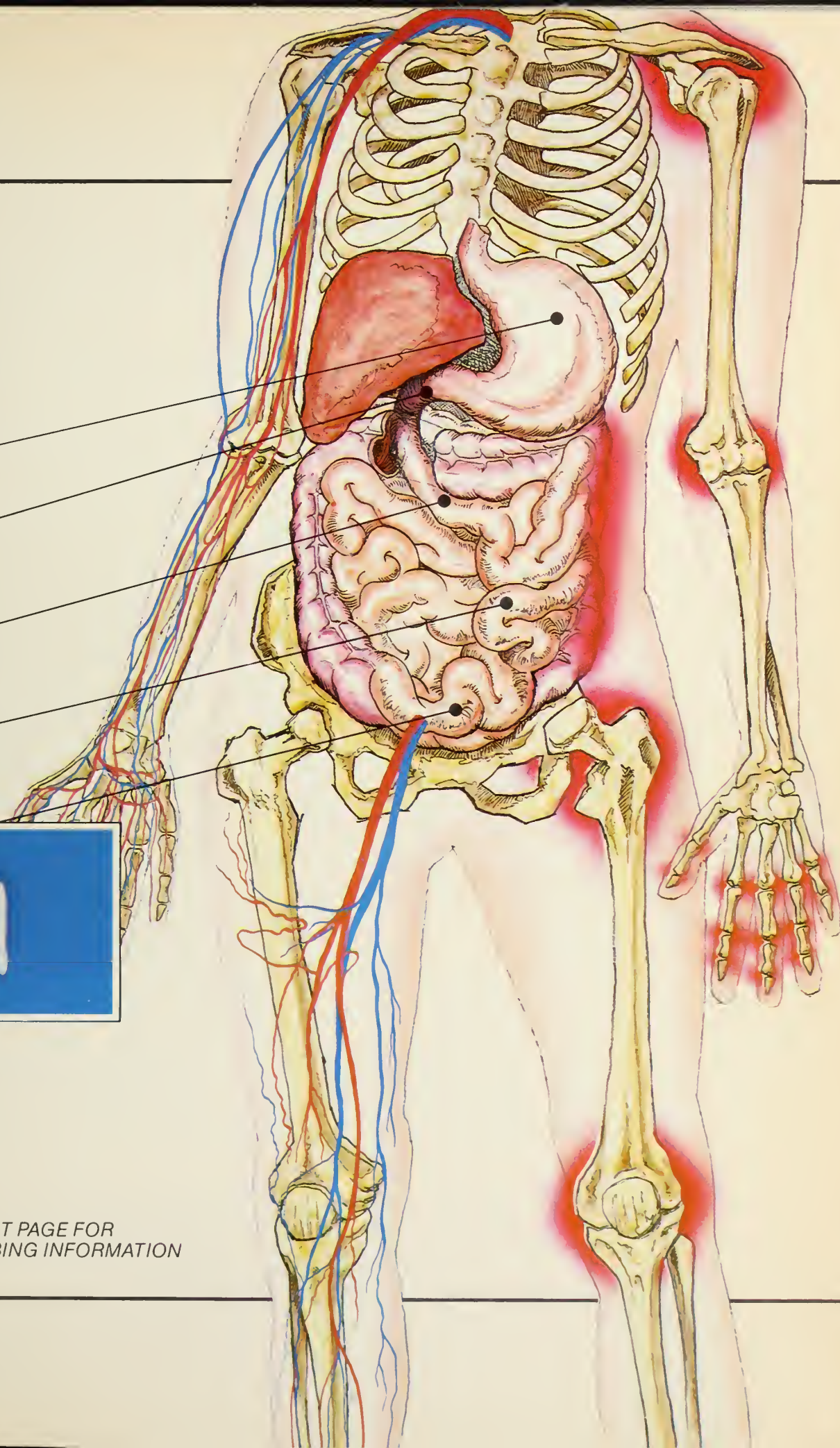
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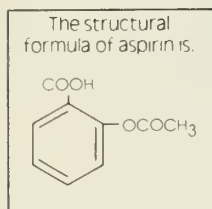


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ZORprin (ASPIRIN) Zero-Order Release

DESCRIPTION: Each capsule-shaped tablet of Zorprin contains 800 mg of aspirin, formulated in a special matrix to control the release of aspirin after ingestion. The controlled availability of aspirin provided by Zorprin approximates zero-order release, the *in vitro* release of aspirin from the tablet matrix is linear and independent of the concentration of the drug. **CLINICAL PHARMACOLOGY:** Aspirin, as contained in Zorprin, is a salicylate that has demonstrated anti-inflammatory and analgesic activity. Its mode of action as an anti-inflammatory and analgesic agent may be due to the inhibition of synthesis of prostaglandins, although its exact mode of action is not known. \square Zorprin dissolution is pH-dependent. *In vitro* studies have shown very little aspirin to be released in acidic solutions, whereas, Zorprin releases the majority of its aspirin (90%) in a zero-order mode at a neutral to alkaline pH. It is this pH dependence of Zorprin that reduces direct contact between aspirin and the gastric mucosa, resulting in a reduction of its gastrointestinal side-effect potential. \square Bioavailability data for Zorprin have confirmed that plasma levels of salicylic acid and acetylsalicylic acid can be measured 24 hours after a single oral dose. This substantiates a twice daily dose regimen. Multiple dose bioavailability studies showed similar steady-state salicylate levels for Zorprin as for conventional release aspirin using the same total daily dose. Long-term monitoring of salicylate levels showed no signs of accumulation once steady-state levels were reached (4-6 days). \square Studies of *in vivo* prostaglandin levels (PGE₂) have shown Zorprin plasma levels of salicylic acid and acetylsalicylic acid to reduce PGE₂ levels 14 hours after a single oral 800 mg dose while an equivalent dose of aspirin produced a reduction of PGE₂ levels only through six hours. Zorprin's effect on prostaglandins other than PGE₂ has not been determined. \square Salicylates are excreted mainly by the kidney, and from studies in humans it appears that salicylate is excreted in the urine as free salicylic acid (10%); salicylic acid (75%); salicylic phenolic (10%); acyl glucuronides (5%) and gentisic acid (<1%). **INDICATIONS & USAGE:**



Zorprin is indicated for the treatment of rheumatoid arthritis and osteoarthritis. The safety and efficacy of Zorprin have not been established in those rheumatoid arthritis patients who are designated by the American Rheumatism Association as Functional Class IV (incapacitated, largely or wholly bedridden, or confined to wheelchair, little or no self-care). \square In patients treated with Zorprin for rheumatoid arthritis and osteoarthritis, the anti-inflammatory action of Zorprin has been shown by reduction in pain, morning stiffness and disease activity as assessed by both the investigators and patients. \square In clinical studies in patients with rheumatoid arthritis and osteoarthritis, Zorprin has been shown to be comparable to conventional release aspirin in controlling the aforementioned signs and symptoms of disease activity and to be associated with a statistically significant reduction in the milder gastrointestinal side effects (see ADVERSE REACTIONS). Zorprin may be well tolerated in some patients who have had gastrointestinal side effects with conventional release aspirin, but these patients when treated with Zorprin should be carefully followed for signs and symptoms of gastrointestinal bleeding and ulceration. \square Since there have been no controlled trials to demonstrate whether or not there is any beneficial effect or harmful interaction with the use of Zorprin in conjunction with other nonsteroidal anti-inflammatory agents (NSAIs), the combination cannot be recommended (see Drug Interactions). **Because of its relatively long onset of action, Zorprin is not recommended for antipyresis or for short-term analgesia.** \square **CONTRAINDICATIONS:** Zorprin should not be used in patients known to be hypersensitive to salicylates or in individuals with the syndrome of nasal polyps, angioedema, bronchospastic reactivity to aspirin, renal or hepatic insufficiency, hypoprothrombinemia or other bleeding disorders. Zorprin is not recommended for children under 12 years of age, it is contraindicated in all children with fever accompanied by dehydration. **WARNINGS:** Zorprin should be used with caution when anticoagulants are prescribed concurrently, since aspirin may depress platelet aggregation and increase bleeding time. Large doses of salicylates may have hypoglycemic action and enhance the effect of the oral hypoglycemics, concomitant use therefore is not recommended. However, if such use is necessary, dosage of the hypoglycemic agent must be reduced. The hypoglycemic action of the salicylates may also necessitate adjustment of the insulin requirements of diabetics. \square While salicylates in large doses have a uricosuric effect, smaller amounts may reduce water excretion and increase serum uric acid. \square **USE IN PREGNANCY:** Aspirin can harm the fetus when administered to pregnant women. Aspirin interferes with maternal and infant hemostasis and may lengthen the duration of pregnancy and parturition. Aspirin has produced teratogenic effects and increases the incidence of stillbirths and neonatal deaths in animals. \square If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. \square Aspirin should not be taken during the last 3 months of pregnancy. **PRECAUTIONS:** Appropriate precautions should be taken in prescribing Zorprin for patients who are known to be sensitive to aspirin or salicylates. Particular care should be used when prescribing this medication for patients with erosive gastritis, peptic ulcer, mild diabetes or gout. As with all salicylate drugs, caution should be exercised in prescribing Zorprin for those patients with bleeding tendencies or those on anticoagulants. \square In order to avoid exacerbation of disease or adrenal insufficiency, patients who have been on prolonged corticosteroid therapy should have their therapy tapered slowly rather than discontinued abruptly when Zorprin is made a part of the treatment program. \square Patients receiving large doses of aspirin and/or prolonged therapy may develop mild salicylate intoxication (salicylism) that may be reversed by dosage reduction. \square Salicylates can produce changes in thyroid function tests. \square Salicylates should be used with caution in patients with severe hepatic damage, preexisting hypoprothrombinemia, Vitamin K deficiency and in those undergoing surgery. \square Since aspirin release from Zorprin is pH dependent, it may change in those conditions where the gastric pH has been increased as a result of antacids, gastric secretion inhibitors or surgical procedures. **Drug Interactions:** (See **WARNINGS**) Aspirin may interfere with some anticoagulant and antidiabetic drugs. Drugs which lower serum uric acid by increasing uric acid excretion (uricosurics) may be antagonized by the concomitant use of aspirin, particularly in doses less than 2.0 grams/day. Nonsteroidal anti-inflammatory drugs may be competitively displaced from their albumin binding sites by aspirin. This effect may negate the clinical efficacy of both drugs. Also, the gastrointestinal inflammatory potential of nonsteroidal anti-inflammatory drugs may be potentiated by aspirin. The combination of alcohol and aspirin may increase the risk of gastrointestinal bleeding. \square Aspirin may enhance the activity of methotrexate and increase its toxicity. \square Sodium excretion produced by spironolactone may be decreased in the presence of salicylates. Concomitant administration of other anti-inflammatory drugs may increase the risk of gastrointestinal ulceration. Urinary alkalinizers decrease aspirin's effectiveness by increasing the rate of salicylate renal excretion. Phenobarbital decreases aspirin's effectiveness by enzyme induction. **Pregnancy Category D.** See **WARNINGS** Section. **Nursing Mothers:** Salicylates have been detected in the breast milk of nursing mothers. Because of the potential for serious adverse reactions from aspirin in nursing infants, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the benefit of the drug to the mother. **ADVERSE REACTIONS: Hematologic:** Aspirin interferes with hemostasis. Patients with a history of blood coagulation defects or receiving anti-coagulant drugs or with severe anemia should avoid Zorprin. Aspirin used chronically may cause a persistent iron deficiency anemia. **Gastrointestinal:** Aspirin may potentiate peptic ulcer, and cause stomach distress or heartburn. Aspirin can cause an increase in occult bleeding and in some patients massive gastrointestinal bleeding. However, the greatest release of active drug from Zorprin is designed to occur in the small intestine over a period of time. This has resulted in fewer symptomatic gastrointestinal side effects. **Allergic:** Allergic and anaphylactic reactions have been noted when hypersensitive individuals have taken aspirin. Fatal anaphylactic shock, while not common, has been reported. **Respiratory:** Aspirin intolerance, manifested by exacerbations of bronchospasm and rhinitis, may occur in patients with a history of nasal polyps, asthma, or rhinitis. The mechanism of this intolerance is unknown but may be the result of aspirin-induced shunting of prostaglandin synthesis to the lipoxygenase pathway and the liberation of leukotrienes, e.g. slow-reacting substance of anaphylaxis. **Dermatologic:** Hives, rashes, and angioedema may occur, especially in patients suffering from chronic urticaria. **Central Nervous System:** Taken in overdoses, aspirin provides stimulation which may be manifested by tinnitus. Following initial stimulation, depression of the central nervous system may be noted. **Renal:** Aspirin rarely may aggravate chronic kidney disease. **Hepatic:** High doses of aspirin have been reported to produce reversible hepatic dysfunction. **OVERDOSAGE:** Overdosage, if it occurs, would produce the usual symptoms of salicylism: tinnitus, vertigo, headache, confusion, drowsiness, sweating, hyperventilation, vomiting or diarrhea. Plasma salicylate levels in adults may range from 50 to 80 mg/dl in the mildly intoxicated patient to 110 to 160* mg/dl in the severely intoxicated patient. An arterial blood pH of 7.1 may indicate serious poisoning. The clearance of salicylates in children is much slower than adults and should receive due consideration when aspirin overdoses occur in infants; salicylate half-lives of 30 hours have been reported in infants 4-8 months old. Treatment for mild intoxication should include emptying the stomach with an emetic, or gastric lavage with 5% sodium bicarbonate. Individuals suffering from severe intoxication should, in addition, have forced diuresis by intravenous infusions of sodium bicarbonate and dextrose or sodium lactate. In extreme cases, hemodialysis or peritoneal dialysis may be required. \square (*A plasma salicylate level of 160 mg/dl in an adult is usually considered lethal.) **DOSEAGE & ADMINISTRATION:** In order to achieve a zero-order release, the tablets of Zorprin should be swallowed intact. \square Breaking the tablets or disrupting the structure will alter the release profile of the drug. \square It is recommended that Zorprin be taken with sufficient quantities of fluids (8 oz. or more). **Adult Dosage:** For mild to moderate pain associated with rheumatoid arthritis and osteoarthritis, the recommended initial dose of Zorprin is 1600 mg (2-800 mg tablets) twice a day. Because of Zorprin's prolonged release of aspirin into the bloodstream, Zorprin tablets may be taken as a b.i.d. dose. Further adjustment of the dosage should be determined by the physician, based upon the patient's response and needs. Since it will take 4-6 days to reach steady-state levels of salicylic acid with Zorprin, it is recommended dosages be given for at least one week before further adjustment. In general, patients with rheumatoid arthritis seem to require higher doses of Zorprin than do patients with osteoarthritis. **Zorprin is not recommended for children below the age of 12.** **HOW SUPPLIED: Zorprin Tablets 800 mg;** plain, white capsule-shaped tablets. \square Bottles of 100 Tablets—NDC 0524-0057-01. **Caution:** Federal law prohibits dispensing without prescription. \square U.S. Patent No. 4,308,251. **Manufactured and Distributed by: BOOTS PHARMACEUTICALS, INC., Shreveport, Louisiana 71106 U.S.A.**

12/8/83 0057-04

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Before prescribing, see complete prescribing information in SK&F CO. literature or PDR. The following is a brief summary.

WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide, dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Anti-hypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

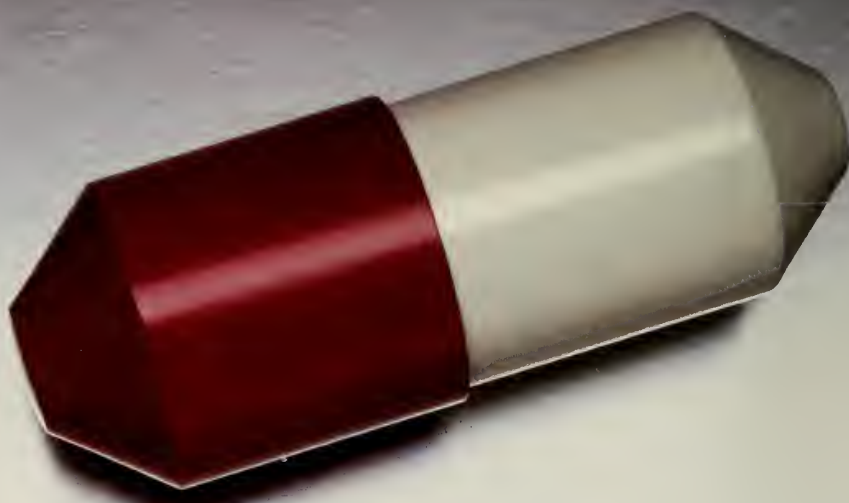
Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances, postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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Serum K^+ and BUN should be checked periodically (see Warnings and Precautions).



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- Studied extensively in the sleep laboratory—the most valid environment for measuring hypnotic efficacy.¹⁻¹²
- Studied in over 200 clinical trials involving over 10,000 patients.¹³
- During long-term therapy, which is seldom required, periodic blood, kidney and liver function tests should be performed.
- Contraindicated in patients who are pregnant or hypersensitive to flurazepam.
- Caution patients about drinking alcohol, driving or operating hazardous machinery during therapy.



References: 1. Kales A et al: *J Clin Pharmacol* 17:207-213, Apr 1977 and data on file, Hoffmann-La Roche Inc., Nutley, NJ. 2. Kales A: Data on file, Hoffmann-La Roche Inc., Nutley, NJ. 3. Zimmerman AM: *Curr Ther Res* 13:18-22, Jan 1971. 4. Kales A et al: *JAMA* 241:1692-1695, Apr 20, 1979. 5. Kales A, Scharf MB, Kales JD: *Science* 201:1039-1041, Sep 15, 1978. 6. Kales A et al: *Clin Pharmacol Ther* 19:576-583, May 1976. 7. Kales A, Kales JD: *Pharmacol Physicians* 4:1-6, Sep 1970. 8. Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. 9. Dement WC et al: *Behav Med* 5:25-31, Oct 1978. 10. Vogel GW: Data on file, Hoffmann-La Roche Inc., Nutley, NJ. 11. Karacan I, Williams RL, Smith JR. The

sleep laboratory in the investigation of sleep and sleep disturbances. Scientific exhibit at the 124th annual meeting of the American Psychiatric Association, Washington, DC, May 3-7, 1971. 12. Pollak CP, McGregor PA, Weitzman ED: The effects of flurazepam on daytime sleep after acute sleep-wake cycle reversal. Presented at the 15th annual meeting of the Association for Psychophysiological Study of Sleep, Edinburgh, Scotland, June 30-July 4, 1975. 13. Data on file, Hoffmann-La Roche Inc., Nutley, NJ.

Dalmane® (flurazepam HCl/Roche)

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Effective in all types of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakening; in patients with recurring insomnia or poor sleeping habits; in acute or chronic medical situations requiring restful sleep. Objective sleep laboratory data have shown effectiveness for at least 28 consecutive nights of administration. Since insomnia is often transient and intermittent, prolonged administration is generally not necessary or recommended. Repeated therapy should only be undertaken with appropriate patient evaluation.

Contraindications: Known hypersensitivity to flurazepam HCl; pregnancy. Benzodiazepines may cause fetal damage when administered during pregnancy. Several studies suggest an increased risk of congenital malformations associated with benzodiazepine use during the first trimester. Warn patients of the potential risks to the fetus should the possibility of becoming pregnant exist while receiving flurazepam. Instruct patient to discontinue drug prior to becoming pregnant. Consider the possibility of pregnancy prior to instituting therapy.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. **Adults:** 30 mg usual dosage; 15 mg may suffice in some patients. **Elderly or debilitated patients:** 15 mg recommended initially until response is determined.

Supplied: Capsules containing 15 mg or 30 mg flurazepam HCl.

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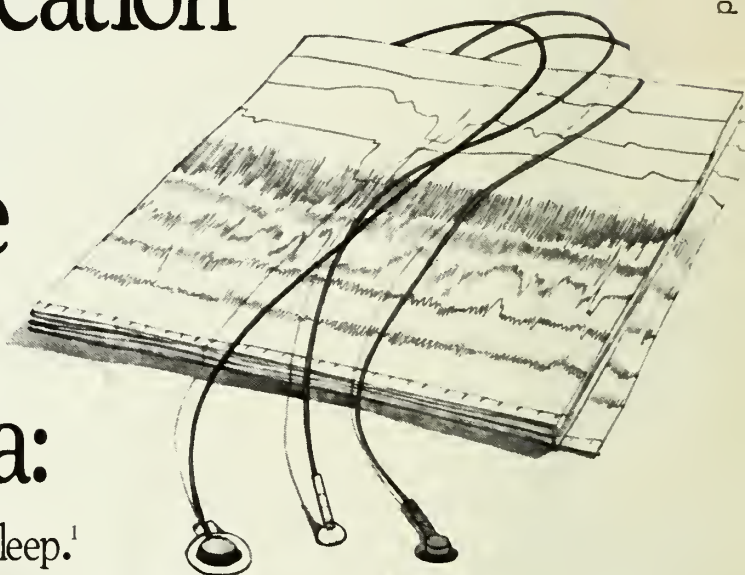
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Please see summary of product information on reverse side.

Dalmane® [Ⓝ]
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Rhode Island Medical Journal

March 1984
Volume 67, Number 3

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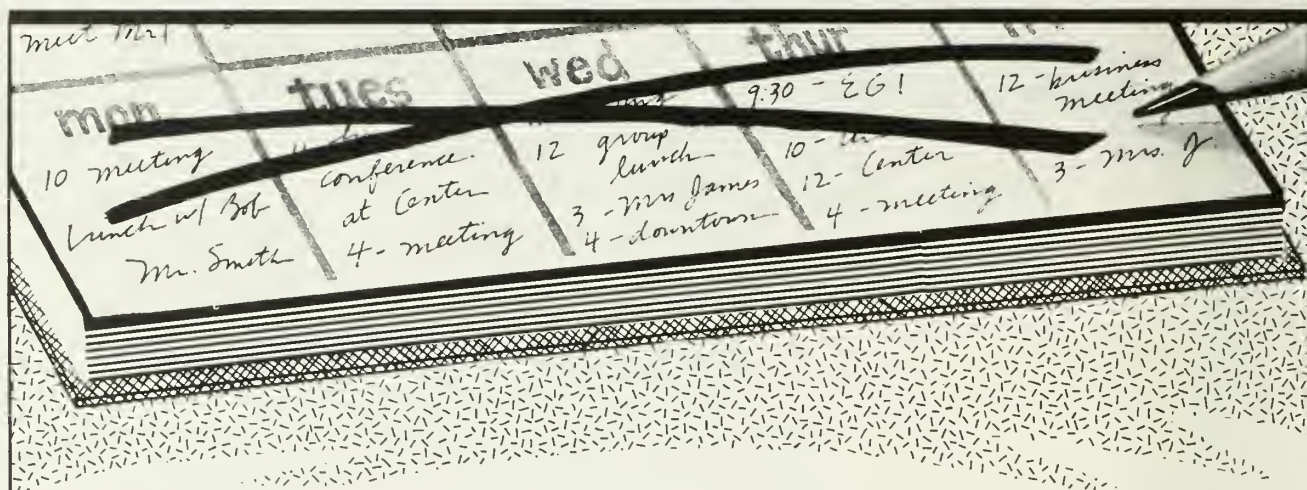
For more on
dimethyl sulfoxide
(DMSO), see page 119



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Newsletter

RHODE ISLAND MEDICAL SOCIETY
March 1984

Charles P. Shoemaker, Jr., MD, President
Wendy J. Smith, Editor

ACTUARY TO REPRESENT SOCIETY DURING MALPRACTICE RATE HEARINGS

The Council of the Rhode Island Medical Society recently authorized retention of a consultant actuary to review an anticipated rate hike from the Medical Malpractice Joint Underwriting Association (JUA) of Rhode Island. The JUA reportedly plans to seek a 17 per cent increase for basic coverage during the 1984-1985 premium year, and a 60 per cent increase for excess limits coverage. The JUA requests will be the subject of hearings before the Department of Business Regulation later this year.

In previous years, the actuarial consulting firm of Woodward & Fondiller, New York, has been retained to represent RIMS at the JUA rate hearings. As a result of testimony presented by James Stergiou, the firm's senior vice-president, the Department of Business Regulation in 1983 limited the requested 64 per cent increase to 24 per cent for basic coverage and denied a proposed JUA hike for excess limits coverage.

In other actions at its February 6 meeting, the Council:

- authorized formation of a general partnership to finance the renovation of the Cooper property which adjoins the Medical Society Building on Hayes Street. Under an agreement with Kates Properties and Citizens Bank, the Society will retain title to the land and receive ground rent under a 20-year lease arrangement with rental income to go to the limited partners. At the end of the land lease, the Society may either purchase the building or renew the land lease.

The action was taken to protect the value of the Medical Society Building and the land at 106 Francis Street. Kates Properties plans to develop the Cooper site as a small office building.

- heard a detailed presentation from Dr Frederick S. Crisafulli, Vice-President and Medical Director, Health Care Review, Inc. (formerly Rhode Island PSRO). The group sought the Society's endorsement of its application for designation as the professional review organization (PRO) for the state. As a PRO, Health Care Review would be responsible for "reviewing the cost and quality" of care provided to hospitalized Medicare patients. He noted that Health Care Review will play a pivotal role in assuring that Medicare cases are assigned to the appropriate diagnosis-related group (DRG) category. The Council withheld action on the request and authorized continued meetings with the leadership of Health Care Review to discuss peer review activities.
- supported moves to name the presently unnamed state laboratory building in honor of Charles V. Chapin (1856-1941), internationally renowned for his work in public health.
- asked the Department of Social Services and Rehabilitation to accept computerized statements for physician services to Medicaid patients.
- referred a request from the Woonsocket District Medical Society concerning Medicaid reimbursement levels to the Medical Economics Committee.
- authorized Society President Dr Charles P. Shoemaker, Jr. to discuss recent membership concerns about delayed and reduced payments from Blue Cross & Blue Shield with Blues president Douglas J. McIntosh.
- noted that Drs Richard Bertini, Roger Fontaine, Mary D. Lekas, Kenneth Nanian, and Charles P. Shoemaker, Jr have been appointed to the Nominating Committee.

(continued)

APR 03 1984

BOSTON, MA

COUNCIL MEETS IN FEBRUARY (continued)

- supported actions by the RI Department of Health to increase the per diem rate for members of the Board of Examiners in Medicine to a level "commensurate with their training, expertise, and professional activities." Board members, who are responsible for reviewing applications for physician licenses, currently receive \$20 a day.

CORRECTION

The Society's 1983 budget figures were incorrectly reported in the February News-letter. The report should have noted that total RIMS receipts for 1983 were \$441,696 and total expenditures were \$404,038.

RHODE ISLAND LEGISLATURE CONSIDERS OPTOMETRIC DRUG BILL

In a joint action, the Society and the RI Ophthalmological Society are opposing proposed legislation which would permit optometrists to prescribe therapeutic drugs for ocular diseases. While optometrists in 37 states, including Rhode Island, may use drugs for diagnostic purposes, prescription of therapeutic agents by optometrists is allowed only in North Carolina and West Virginia. The Society and the state's ophthalmologists have labeled the bill, introduced by Reps Joseph L. Casinelli and Frank J. Anzeveno, as a "public health threat" since only physicians have the training and experience to deal with the systemic effects of therapeutic drugs. The bill has been assigned to the House Corporations Committee, chaired by Rep Aldo Freda.

In other actions, the General Assembly currently is considering the following proposals:

- Medicare assignment: H 7183 would require physicians in Rhode Island to accept the Medicare reimbursement as "payment in full" for their services. Another House measure would call upon the US Congress to "enact legislation mandating physician acceptance of assignment of Medicare benefits as a condition of participation in the Medicare program." The Society objected to both bills, sponsored by Rep Anthony

Cardente, since they would result in higher out-of-pocket expenses for the elderly and force physicians out of the program.

- Pacemakers: H 7522 (Rep Armand E. Battastini) would require hospitals to establish committees to review all pacemaker insertions on a prospective basis.
- Laboratories: H 7180 (Rep Anthony Cardente) would permit any person to obtain a blood test and the results from a clinical laboratory without a physician referral.
- Emergency number system: Two bills, S 0226 and H 7304, would provide funds to implement a 911 emergency number system in the state. RIMS met with representatives of New England Bell on several occasions to urge the phone company's support of a 911 mechanism.
- Malpractice: H 7430 (Reps Francis A. Gaschen and Roger N. Begin) would retrospectively extend the 3-year statute of limitations to alleged acts of malpractice not subject to the present limitation which occurred before May 1981.
- Living will: S 0009 (Sen Lila Sapin-isley) would provide a mechanism for a "living will" permitting attending physicians to withhold extraordinary life-sustaining medical procedures. It also would protect physicians and others from civil and criminal liability.
- Insurance forms: H 7522 (Rep Battastini) would prohibit physicians and their employees from requiring patients to sign blank insurance forms before medical services are provided.
- Impaired drivers: Another bill sponsored by Rep Battastini (H 7523) would exempt physicians from civil liability if they report conditions which may affect a "person's ability to drive" to the Registry of Motor Vehicles.

The only bill to be enacted as of this writing was the "Health Care Affordability Act of 1984," which requires the Hospital Assn.
(continued)

of Rhode Island, Blue Cross & Blue Shield, and the state budget office to approve all hospital capital expenditures on the basis of the state's ability to "afford" them. For more on the new legislation, see page 109 of this issue.

STAFF CHANGES AT THE SOCIETY

Dr Norman A. Baxter, RIMS Executive Director, recently announced that Brian R. Clarke, Assistant Executive Director, has accepted a position at Blue Cross & Blue Shield of Rhode Island, effective April 1. Clarke, who joined the Society's staff in February 1982, currently is responsible for tracking the Society's legislative activities.

SWEENEY NAMED ACTING PRESIDENT OF HARI

Effective March 1, William S. Sweeney was named acting president of the Hospital Association of Rhode Island (HARI), replacing the retiring president Wade C. Johnson. Johnson, who announced his retirement plans last year, has been the chief executive officer at HARI since 1955 and was its first full-time employee. Sweeney, associated with the organization since 1969, most recently served as senior vice president. According to Frank A. Delmonico, Chairman, Board of Trustees, a national search for a new association president is underway.

BROWN ESTABLISHES NEW CORPORATION

The Brown University Research Foundation (BURF) and Applied DNA Systems, Pittsburgh,

recently announced formation of a jointly-held corporation for the "commercial development and marketing of a new chemotherapy diagnostic technique."

Ownership of the new corporation, Analytical Biosystems Corporation, is divided equally between the foundation and the Pittsburgh company. Applied DNA Systems, according to a press release from Brown, supplied more than \$300,000 in initial capitalization. The foundation relinquished its patent rights to the new technique.

Developed at Brown University by Dr M. Boris Rotman, Professor of Medical Science, the test, through its close approximation of in vivo conditions, will eventually allow clinicians to determine the most effective course of chemotherapy for individual cancer patients. The technique involves an artificial organ device which grows solid masses of tumor tissue in days. A highly sensitive flow fluorometer analyzes the effect of a given chemotherapeutic agent, or a combination of drugs and radiation therapy, on the tumor mass.

The annual US market for chemotherapy testing is approximately \$300 million. The new corporation projects its potential share of the market to be 40 per cent within ten years.

The Pittsburgh company specializes in commercial applications of genetic and biotechnological research. The foundation was created to "promote research at the university . . . and create links for research support between the Brown University and industry."

PRACTICE MANAGEMENT QUESTION OF THE MONTH:

HOW DOES DIAGNOSIS-RELATED GROUP REIMBURSEMENT AFFECT MY OFFICE PATIENTS?

The recently-implemented prospective payment system for hospitalized Medicare patients currently does not affect the office practices of physicians. It should be emphasized, however, that a similar reimbursement formula for outpatients and private patients may be mandated within the next several years. This column will present a brief summary of the diagnosis-related group (DRG) based reimbursement system, current Medicare requirements for hospitalized patients, federal proposals to extend DRGs, and suggested further readings.

What is a DRG?

Effective October 1, 1983, reimbursement for hospitalized Medicare patients is based on assignment of a diagnosis-related group (DRG) in contrast to the traditional payment method based on the actual costs of providing medical care. Originally devel-

oped by Yale University researchers as a means of utilization review, the DRG system is simply a way of classifying patients on the basis of diagnosis. Five pieces of information are necessary to assign a patient to a DRG: the principal diagnosis and up to four complications, the treatment procedures performed, age, sex, and discharge status. This data is submitted by the hospital to the fiscal intermediary which is responsible for determining the appropriate DRG and calculating reimbursement levels.

While the actual reimbursement formulas are quite complex, payments generally are the product of two factors, the "DRG rate" and the "dollar rate." The DRG rate is an index number which represents the relative hospital resources which are used, on average, for providing inpatient services. The weights apply equally to all hospitals. The dollar rate, for a three-year transition period which started last October, is a function of two factors: a federally-established dollar rate and a specific rate based on the cost experience of each hospital.

All hospitals which participate in the Medicare program are covered under the system except for psychiatric, rehabilitation, long-term, and pediatric hospitals; distinct psychiatric and rehabilitation units within general hospitals or other facilities; hospitals in the US territories; and hospitals in states with an approved waiver.

What are the implications of DRGs for office practices?

As yet, the DRG system has no impact on either private hospitalized patients or outpatients, including Medicare beneficiaries. Congress currently is considering several proposals which, if implemented, would have serious ramifications for both office and hospital practices. The most significant of these is a bill jointly sponsored by Sen Edward Kennedy (D., MA) and Rep Richard Gephardt (D., MO) which would require all states to regulate hospital and physician payments or submit to a national DRG based payment system. Under the so-called "all-payer hospital and physician cost containment plan," states would have three options for compliance. If they reject all three, a national mechanism, comparable to the existing DRG methodology for hospitalized Medicare patients, would be mandated. The implications for physicians and their patients are especially troublesome because the national system would also include private patients and physician bills for all outpatient services.

The bill's sponsors claim that it would solve the existing financial problems of Medicare and save the private sector an estimated \$74 billion by 1989.

Rep. Claude Pepper (D., FL) reportedly plans to introduce legislation which would allow hospitals to retain only 50 per cent, as opposed to the current full amount, of the difference between their actual costs and the DRG payment. The bill, which is intended to curtail alleged "windfall" payments to hospitals, also would add outpatient care to the DRG system starting in 1986. While no specific proposals on nursing homes have been introduced, the Congressional Budget Office estimates that expanding the DRG system to skilled nursing facilities and home health agencies would save Medicare an estimated \$2.9 billion by 1989.

For more information . . .

Numerous books and papers concerning DRGs, many of limited value to practicing physicians, have surfaced in recent months. One of the most concise and explicit books available is *DRGs and the Prospective Payment System: A Guide for Physicians*. It is especially valuable because of its focus on the concerns of practicing clinicians. It is available at \$1.00 a copy, plus a \$2.50 handling charge per order, from the Order Department (OP-230), American Medical Association, PO Box 10946, Chicago, Illinois 60640.



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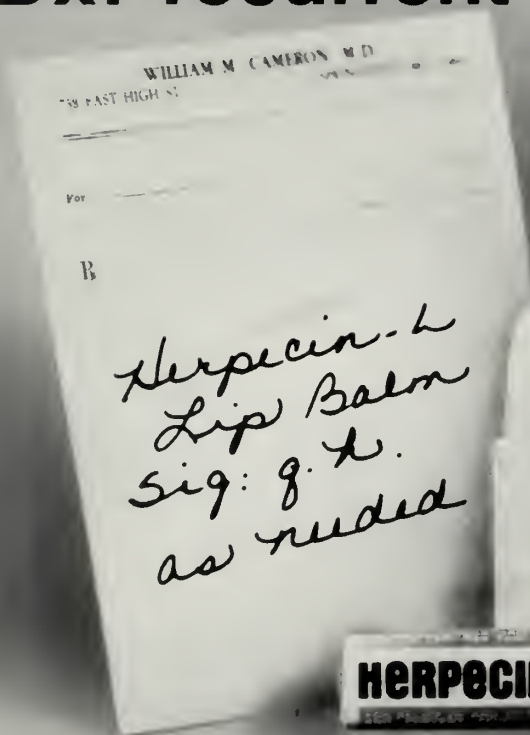
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COVER:

As the result of evidence linking the use of dimethyl sulfoxide (DMSO) to cataracts, the Food and Drug Administration suspended all clinical trials of the substance in 1965. Originally developed as an industrial solvent, DMSO has been approved for veterinary use only and for treatment of intestinal cystitis, a painful but rare bladder condition.

For more on DMSO in Rhode Island, see page 119.

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Health Planning

At its recent Interim Meeting, the American Medical Association again urged the repeal of federally-mandated health planning and reaffirmed its support for the principles of voluntary, locally-based health planning. It encouraged state and county medical associations to consider and implement new and innovative health planning programs. New initiatives in voluntary health planning have emerged in quite a few local communities. They are addressing health planning concerns beyond cost containment. It appears, however, that the local voluntary effort will face unnecessary difficulty in succeeding as long as a state or federal planning mandate remains, particularly in the form of certificate-of-need (CON) legislation.

The AMA Council on Medical Service, which offered these recommendations to the Interim Meeting, concluded that well-documented planning strategies and innovations are the keys to successful planning and resource allocation. "The current federally-mandated planning system," it stated, "is the antithesis of competition. It attempts to displace market forces rather than enhance them and creates vast bureaucracies to administer such regulations that may further impede the implementation of competitive solutions to hospital cost inflation."

Funding for voluntary planning could come from private sources, either in the health care or non-health care sectors, and public funding in the form of categorical or block grants which are not tied to federally-controlled or mandated health planning. Minnesota has repealed its CON law and has received grants from the Robert Wood Johnson Foundation and the US Department of Health and Human Services to establish a feasibility study and pilot project. In North Carolina, the health planning program will be state operated, but will have an advisory committee

appointed by the governor, consisting of members of the state medical society, other health organizations, and private citizens. It is anticipated that this program will be funded by both state and local revenues; solicitations from private business, industry, and insurance companies; and a small tax on insurance policies. Southeastern Pennsylvania has also established a program with multiple financing sources.

The computed tomography (CT) scanner minuet in Rhode Island is an example of the capricious manner in which CON legislation may be administered. After strictly limiting the availability of equipment long after it had been proved to be an essential element in modern diagnosis, the floodgate was then opened and CT scanners are now available virtually everywhere, with, in fact, two in one hospital. We are now again going through the same awkward maneuvers with digital subtraction angiography, and nuclear magnetic resonance is just around the corner.

As of this writing, there is before the Rhode Island General Assembly a bill which provides for the annual setting of a limit on new hospital expenditures.* Testimony supporting the bill was offered by the Rhode Island Business Group on Health, the Coalition for Consumer Justice, the Hospital Association of Rhode Island (HARI), Blue Cross & Blue Shield of Rhode Island, and the state Department of Social and Rehabilitative Services. Under the bill, the state budget office, HARI, and Blue Cross would set an annual limit on the amount that could be spent for new medical projects as the same groups now establish the "maxicaps" allowable for annual hospital expenditures. The limit would be based, it is pro-

* As this issue went to press, it was learned that Governor J. Joseph Garrahy signed House Bill 7103 into law on February 23, 1984. The Health Care Affordability Act of 1984 was approved by the House of Representatives in late January and by the Senate in February.

posed, on an estimate of what the public "can afford to pay."

The Health Services Council, an arm of the state health department, would then rank project proposals in order of importance and approve as many of these as it wishes, within the dollar limitation. This suggests the same log-rolling as currently exists under CON guidelines.

The Rhode Island Medical Society has taken the lonely position of opposing the legislation. In expressing its concerns, it stated that "the setting

of an arbitrary aggregate dollar figure for capital expenditures could restrict patient accessibility to needed services and even make future technological advances unavailable in Rhode Island." In assuming this posture, the Society obviously had in mind the unfortunate delays in procuring CT scanners for Rhode Island hospitals.

Considering the support that this legislation has mustered, it is all too likely that it will be adopted. It is not too late, however, to explore the more attractive route of voluntary planning.

Seebert J. Goldowsky, MD



States' Rights and the Medicare/Malpractice Squeeze

While the term "states' rights" usually is associated with the Civil War, physicians currently are being squeezed in a conflict between the federal government and the states concerning Medicare reimbursement and malpractice premiums.

With the spectre of a bankrupt Medicare system by 1990, both the federal and state governments are taking a hard look at Medicare and Medicaid benefits. Many of the federal proposals call for a sharp cut in payments to physicians and hospitals. One bill currently under Congressional consideration would prohibit hospitals which receive federal funds from awarding clinical privileges to any physician who does not accept assignment of Medicare benefits as "payment in full." Another would freeze physician reimbursement under the Medicare program at the July 1983 level. Since there is an 18-24 month lag between the calculation of prevailing physician charges and Medicare reimbursement levels, this would have the impact of requiring physicians to accept what they charged in 1981 as "payment in full."

In return for concessions on the assignment issue, the AMA has supported a freeze for a limited period. In view of the moderating general rate of inflation, estimated to be 3.8 per cent last year, the prospect of a freeze does not appear to be entirely unreasonable. On the other hand, as a practicing physician, I have seen the costs of providing services, and specifically premiums for malpractice insurance, continue to skyrocket. My own premium increased 24 per cent last year, and another substantial hike is projected for 1984-1985. I immediately think of the early 1970s when physicians faced the combination of a wage/



Charles P. Shoemaker, Jr., MD

price freeze and escalating malpractice premiums. Most of us do not need to be reminded that physicians were subject to a freeze under the Nixon administration long after restrictions were lifted from other segments of the economy.

Administrators of the Medicare program respond to these concerns by claiming that, since few malpractice claims are filed by Medicare patients, the program should not pay for the higher premium costs of malpractice insurance. Yet, it should be obvious that their share of these costs also cannot be transferred either to the Medicaid program or to private "non-federal" patients.

As we face rumors of a freeze and a certain premium hike, it is understandable that physicians feel uneasy. While individual members of

Congress are sympathetic to the problem, the states traditionally have been responsible for malpractice legislation. Some precedent exists, however, for federal involvement with liability issues. In 1957, Congress protected the fledgling nuclear energy industry by creating a fund now totaling some \$570 million to pay for public liability claims resulting from nuclear accidents. While bankruptcy of the Medicare program may not seem comparable to a nuclear accident, the effects may be equivalent if we are forced to ration medical care. Doctor Anthony J. Wing, a prominent nephrologist at St. Thomas Hospital in London, recently was quoted as saying that, of the 2,000 Britons who die each year of renal failure, at least 1,500 are "eminently treatable."

As we continue to restrict payments for Medicare services to physicians and hospitals while allowing malpractice premiums to climb unabated, it is not difficult to anticipate that Medicare services will be rationed. Patients with

"eminently treatable" diseases may well die as a result. In view of the gravity of the situation, it is not unreasonable for the federal government to consider ways of curbing the malpractice crisis. On the state level, physicians probably would find legislative moves to contain medical costs to be more acceptable in return for significant and realistic malpractice reforms.

In short, physicians find themselves caught between potential federal restriction of Medicare payments and uncontrolled liability premiums only nominally regulated by the state. As the squeeze continues, we can anticipate either loud protests or quiet withdrawals from the Medicare program. In either case, the elderly patient will be the loser. Since some state and federal legislators are aware of the problem, the time may be appropriate not only for radical proposals to "cap" medical costs, but also to find ways to limit malpractice premiums.

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SPECIAL REPORT

The American Medical Association and Technology Assessment

Wendy J. Smith

The utilization of radial keratotomy for the treatment of myopia remains an "investigational intervention" at the present time. Moreover, its efficacy is "questionable" and subsequent complications resulting from the procedure are "poorly defined." This was one of the findings reported at the December 1983 meeting of the American Medical Association by the AMA Council on Scientific Affairs as part of its detailed evaluation of the current "state of the art" of technology assessment. While much of the report from the Council focuses on current AMA activities in this area, it also analyzes the efforts of other private and public agencies to evaluate the impact of new and existing medical technologies.

Because of the significance of these evaluations to practicing physicians, an analysis of the report from the AMA Council on Scientific Affairs is presented below. Copies of the complete document are available from the offices of the Rhode Island Medical Society (401/331-3207).

Technology Assessment by the AMA

For more than 20 years, the Council on Scientific Affairs has prepared reports for practicing physicians on numerous technological developments, many of which have attracted considerable professional and public interest because of their controversial nature. During the past four years, reports have been published on such clinical issues as aortocoronary bypass graft surgery, exercise programs for cardiac patients, exercise stress testing, organ transplantation, computed tomographic scanning, and electronic fetal monitoring. In response to the rapid proliferation of medical technology, the AMA formalized this continuing activity and in 1982 launched its Diagnostic and Therapeutic Technology Assess-

ment (DATTA) program. Under the DATTA mechanism, a pool of some 500 physicians nominated by the Council on Scientific Affairs, state medical societies, and national specialty associations serve as expert panelists on specific technological advances.

The DATTA recommendations are intended to evaluate the relative merits of new and existing developments as utilized in medical practice. Based primarily on the "safety" and "efficacy" of a procedure from a clinical perspective, these opinions do not address such issues as cost control and resource allocation. The objective of the program, according to the Council report, is to provide a "ready source of reference information derived from reliable and authoritative sources for practicing physicians."

DATTA recommendations routinely are published in the *Journal of the American Medical Association (JAMA)*. In addition to its evaluation of radial keratotomy, the DATTA program issued opinions on the following advances during the first six months of last year:

Gynecological malignancies: The utilization of CO₂ lasers in the treatment of appropriately selected cervical, vulvar, and vaginal intraepithelial neoplasia and condyloma accuminatum is considered to be "safe and effective."

Diathermy: While the Council reported significant reservations about the superiority of diathermy over other forms of heat therapy, it is "widely accepted as an established practice" for the relief of pain due to minor musculoskeletal conditions. The DATTA panel also noted that ultrasound currently is regarded as "safe and more effective than the older forms of diathermy."

Quantitative electroencephalographic intraoperative monitoring: The utilization of Fast Fourier Transform Analysis has not yet been established as "an effective, predictive, clinical tool for the intraoperative monitoring" of cerebrovascular status.

This analysis is based on Report G of the Council on Scientific Affairs of the American Medical Association to the AMA House of Delegates, December 1983.

The continuing investigation of its role in the surgical patient, however, may well be "warranted," according to the DATTA panel.

Mandatory electrocardiograms prior to elective surgery: Even though there was no agreement as to the definition of middle age, the DATTA panel supported the routine utilization of preoperative EKGs for most middle-aged patients.

Chelation therapy (EDTA) for atherosclerotic disease: The DATTA panel concluded that chelation therapy has not been established as an "acceptable treatment for coronary or other arterial atherosclerosis."

Biofeedback: Biofeedback is regarded as an "established" treatment for headaches, especially those of vascular origin, according to the Council. With the appropriate safeguards and proper selection of patients, the DATTA panel noted that it can be successfully integrated into a therapeutic program for headaches.

Implantable infusion pumps: The DATTA panel commented that implantable infusion pumps provide a "promising technique" for the treatment of selected patients who require chronic intravascular drug therapy. The pumps already are being used under investigational protocols for specific indications and ultimately may be considered as an established modality. The panel said, however, that their use "must remain an investigational procedure" until the completion of several controlled studies which are currently in progress.

Other Technology Assessment Groups

The significant policy implications of new medical advances have stimulated the growth of technology assessment activities by other private and public agencies. Some of these programs, like the AMA/DATTA effort, focus exclusively on the clinical relevance of technological advances while others evaluate the potential impact of new modalities on the costs of medical care and the way that care is delivered.

Two widely-recognized programs are sponsored by professional societies. The Clinical Efficacy Program (CEAP) of the American College of Physicians reviews questioned technologies of significance to the practice of internal medicine. Its reports are based on the clinical judgments of experts and the synthesis of existing data. In response to membership inquiries, the American Hospital Association (AHA) performs assessments of new equipment which con-

centrate on such manufacturing issues as vendor stability, service reliability, and protections against obsolescence. The AHA findings are published in the annual *Guideline Reports*.

In addition to these activities, many medical specialty societies issue reports related to their specialties or address technological subjects in their journals. Under a system established by the American College of Cardiology, as an example, requests for assessments are generally reviewed by the Cardiovascular Procedures Committee and referred to an appropriate subcommittee if necessary. The American Academy of Neurology reviews such requests through its Practice Committee and publishes an annual compilation of its evaluations. The American College of Obstetricians/Gynecologists periodically issues State-of-the-Art Opinions and Technical Bulletins.

Initiatives by three federal agencies are especially important because they attempt to resolve some of the broader economic, social, and fiscal implications of technological advances. The most ambitious undertaking is sponsored by the Office for Medical Application of Research (OMAR) of the National Institutes of Health which, in addition to the issues of safety and efficacy, evaluates medical technologies in terms of their fiscal, ethical, and legal implications. These issues formerly were considered by the National Center for Health Care Technology, which was dismantled as an austerity move by the Reagan Administration. OMAR bases its assessments on the recommendations of scientific experts, a limited amount of original research, and data from the NIH consensus development program. Its findings are published by the National Institutes of Health and frequently in *JAMA*.

Recommendations from the Office of Health Technology Assessment of the US Public Health Service have widespread fiscal implications as they are used by the Health Care Financing Administration (HCFA) to determine Medicare coverage. Other insurance carriers and service plans, such as Blue Shield, often rely on HCFA determinations as a basis for their own coverage decisions.

The Office of Technology Assessment (OTA) of the US Congress accepts requests for studies from any OTA director or member of Congress. It does not perform original research, but synthesizes existing data. While social and ethical considerations are reviewed, the primary focus on OTA investigations is on the cost, efficacy, and, occasionally, safety of new technological advances. The major emphasis of its work has been

on documenting the need for more original research on medical technology.

Institute of Medicine

In early 1983, the Institute of Medicine (IOM) convened a committee to investigate the "feasibility and utility" of creating a new collaborative venture between the public and private sectors to evaluate technological advances in clinical medicine.

In a sweeping draft report, the IOM committee described the proposed composition and functions of a new entity which would cost an estimated \$1 million annually to operate. Its proposed scope of work would include a review of drugs, devices, medical technologies, and surgical procedures, and "the knowledge necessary for their appropriate use in the delivery of patient care." Moreover, medical technology assessment by this new group would include the "development and evaluation of evidence concerning effectiveness, safety, cost, cost-effectiveness, and, when appropriate, the policy implications of the development and use of a specific technology, commensurate with its stage of development. It may include the evaluation of knowledge, professional competence, indications, facilities, and personnel necessary for appropriate use."

The draft committee report proposed to leave the new entity under the auspices of the Institute of Medicine while funding from a variety of sources in the public and private sectors is sought. As of this writing, no further action has been taken on these recommendations.

Prospective Payment Assessment Commission

Of more immediate importance to practicing physicians are the 1983 amendments to the Social Security Act which authorized the establishment of a Prospective Payment Assessment Committee (to be known as PROCAP). This committee will be responsible for developing a diagnosis-related group (DRG) based reimbursement system for physicians and other providers. Congressional staff have indicated that the annual funding of PROCAP from the Medicare trust fund and other sources may reach some \$20 million a year.

In addition to its continuing DATTA activities,

the AMA Council on Scientific Affairs reported that it is currently identifying potential nominees to serve on PROCAP. It is likely that the activities of the Prospective Payment Assessment Commission will have considerable influence on the day-to-day practice of medicine, although its extent and direction remain unclear at the present time.

Discussion

Demands for the reliable evaluation of existing and new medical technologies have become more strident in the recent past, primarily in response to pressure from several sources. While hospitals and federal payment agencies require assistance in making prudent purchases, the Health Care Financing Administration and private insurance carriers seek rational data for setting reimbursement levels. Some clinical researchers, concerned by substantial revisions in their budgets, have called for support from third-party payers of randomized controlled clinical trials. It is likely that policymakers will regard a sweeping and more critical assessment of medical technologies as the principal means of cost containment. In Rhode Island, at least one legislative commission currently is considering a means to place a maximum limit on all hospital capital acquisitions based on the state's ability to "afford" them.* Most importantly, practicing physicians look for readily-available information as to the impact of technological advances on their clinical decisions.

After reviewing such diverse requirements, the AMA Council on Scientific Affairs concluded that some tensions among the various groups appear to be inevitable. Part of the difficulty is attributable to the fact that previous efforts at technology assessment have concentrated on the "safety and efficacy" of new procedures, while there has been growing support for randomized clinical trials as the basis for "wise reimbursement decisions." As the Council report notes, however, much of the tension is due to the essential dichotomy between practicing physicians and health planners: "Medicine is grounded in the ethic of individual patient care, while payers and health planners are more attuned to the ethic of the greatest good to the greatest number at a reasonable cost." To protect the interests of physicians and their patients, the Council emphasized the importance of participation by the AMA and other medical organizations in the continuing debate on technology assessment.

* As this issue went to press, it was learned that Governor J. Joseph Garrahy signed House Bill 7103 into law on February 23, 1984. The Health Care Affordability Act of 1984 was approved by the House of Representatives in late January and by the Senate in February.



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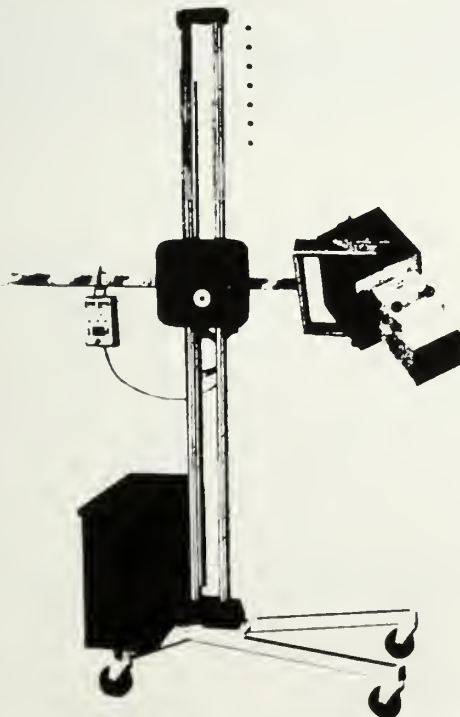
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Clinical Experiences with Dimethyl Sulfoxide (DMSO) in Human Subjects

Approval Must Be Withheld until Safety in Extended Use Is Established

Americo A. Savastano, MD

On behalf of the Squibb Institute of Medical Research, in 1965 I conducted a double-blind clinical trial on the use of aqueous solutions of 90 per cent dimethyl sulfoxide (DMSO), with and without steroids. Two bottles, labeled AKB and AKD, were supplied, and for the brief duration of the study, I did not know which bottle contained DMSO with 0.1 per cent Kenalog® and which contained a pure solution of 90 per cent DMSO.

After I treated a total of 35 cases with the samples, the Food and Drug Administration (FDA) ordered the Squibb Institute to discontinue the study as there was evidence linking the drug to cataracts in laboratory animals. Because of the potential danger of eye damage in human subjects, clinical testing was suspended and has not been resumed except in limited trials. Within the past year, however, extensive television coverage of DMSO has stimulated a resurgence of public interest. Many of these programs typically have presented cases in which dramatic and instantaneous pain relief was claimed. While the substance has been characterized by some as a "miracle drug," its supposed clinical successes remain to be confirmed by rigorous double-blind tests. Until DMSO has been thoroughly studied and the FDA issues a favorable directive, physicians should not recommend its administration for human illnesses.

Americo A. Savastano, MD, is in the private practice of orthopedic surgery in Providence, Rhode Island; Surgeon-in-Chief Emeritus, Division of Orthopaedic Surgery, Rhode Island Hospital; and Clinical Professor of Orthopaedic Surgery, Brown University Program in Medicine. As chairman of the Sports Medicine Committee of the Rhode Island Medical Society, Doctor Savastano has been instrumental in organizing an annual conference on sports medicine held at the University of Rhode Island which attracts physicians and sports trainers from throughout the country.

What is DMSO?

DMSO is a colorless liquid derived from lignin, a material which naturally binds the cells of trees. Extracted during the industrial manufacture of pulp, it is generally processed in four concentrations of 50, 70, 90, or 100 per cent aqueous solutions. DMSO initially was patented in 1963 by the Crown-Zellerbach Corporation as an industrial solvent. That same year researchers at the University of Oregon Medical School found that DMSO, when topically applied, is quickly absorbed and carried into the circulation. It was reported that its application almost instantly reduced pain and inflammation in the treated area.

Proponents of DMSO have suggested its use primarily for the treatment of scleroderma, a partially-understood collagen disease with rheumatic manifestations. Favorable results also have been claimed in cases of rheumatoid and osteoarthritis, and less frequently, for athlete's foot, bruises, sunburn, bursitis, complications of degenerative disks, frostbite, fungal infections, gout, herpes simplex, neck strains, neuralgias, sprains, and tendinitis. A four per cent aqueous solution has been ingested with reported success in such conditions as colitis, gastritis, and peptic ulcer. It has also been used intravenously to alleviate the pain caused by malignant tumors, leukemia, cardiovascular disease, and spinal cord injuries.

DMSO is commonly used by veterinary physicians to treat ailments in horses, dogs, and cats. The only clinical application to receive FDA approval has been the use of a 50 per cent DMSO solution to treat interstitial cystitis, a painful but rather rare bladder dysfunction. Despite the FDA proscription, some athletic trainers favor the use of 90 per cent and stronger aqueous solutions for their athletes. In addition to the danger of cataracts, other adverse reactions in human subjects include local erythema, halitosis, headache, and, occasionally, nausea and vomiting.

Current Legal Status of DMSO

Except where it is administered for experimental purposes under FDA approval and for treatment of interstitial cystitis, DMSO use in human subjects is legally permitted only in California, Florida, Louisiana, and Oregon. Its use by patients also is permitted in Canada and in Mexico, where numerous "DMSO clinics" specialize in treating Americans unable to obtain the substance at home. Some of these clinics also prescribe other anti-inflammatory medications for their US patients.

Clinical Findings

Thirty-five human subjects treated in 1965 received topical application of DMSO with 0.1 per cent Kenalog® or an unadulterated DMSO solution at 90 per cent strength. The contents of the bottles remained unknown to me at the time of the study, and none of the subjects received the drug either orally or intravenously. The study results were correlated as to the sex, age, and race of the subject, the amount of solution used, the joint involved, and the duration of treatment. It recorded the effect of DMSO on pain relief, swelling, range of motion, morning stiffness, and tenderness. In addition, the diagnosis, adverse reactions, final therapeutic results, and drugs used prior to DMSO treatment were noted.

Eighteen patients were treated with the DMSO solution containing the steroid. Treatment consisted of the topical application of 8 ml which was reapplied as needed up to three times daily. The group included five males and 13 females, all were Caucasian, and their ages ranged from 25 to 75 years. Six of the subjects were diagnosed as having osteoarthritis of the knee; two, traumatic myositis of the shoulder; and one each, probable sprain of the shoulder, osteoarthritis of the shoulder, subdeltoid bursitis of the shoulder, rheumatoid arthritis of both wrists, contusion of the right hip, and contusion of the right elbow.

Of the 18 subjects, two received immediate pain relief, two improved after two days of treatment, three after four days, five after five days, and three after seven days. Three of the patients demonstrated no improvement after a week of treatment.

The results were equivocal. The swelling which was evident in 10 patients before DMSO treatment was reduced in four, apparently as a result of the therapy. Eight of the subjects had initially presented with no signs of inflammation. The range of motion increased in nine cases, the evi-

dence of morning stiffness was reduced in 13, and the presence of tenderness decreased in 14. Thirteen subjects suffered no adverse reactions, while five developed a local erythema. All subjects experienced the so-called "garlic breath," a common manifestation of DMSO use. The final therapeutic result was considered excellent in five, good in six, fair in three, and poor in four.

Seventeen patients were treated with a 90 per cent aqueous solution of DMSO with the same dosage schedule as the other cohort. In this group were 15 females and two males, all Caucasians, ranging in age from 24 to 87 years. The diagnoses in the treated patients included five cases of traumatic myofascitis of the back; four of osteoarthritis of the knee; two each of fibrositis of the shoulder and tennis elbow; and one each of medial epicondylitis of the elbow, sprain of neck, trochanteric bursitis of the hip, and sprain of the acromioclavicular joint. Two subjects obtained immediate pain relief, one after three days of treatment, three after four days, one after five days, one after six days, and five after one week. Four patients demonstrated no improvement.

The results were as follows. Swelling was initially present in only six of the 17 patients, and all exhibited a decrease in local inflammation. The range of motion improved in 11 cases, the presence of morning stiffness decreased in 14, and the degree of tenderness was also reduced in 14. The only adverse reaction was local erythema in three cases, although all subjects developed garlic breath. The final therapeutic result was regarded as excellent in six patients, good in eight, and poor in three.

Previous therapy did not appear to alter the clinical results of DMSO treatment. One patient had taken Arthralgen® for several weeks and another received three local injections of Xylocaine® and DepoMedrol® to relieve trochanteric bursitis. Three cases had been treated with joint aspirations followed by an injection of DepoMedrol®. One patient had, on three separate occasions, taken 25 mg Indocin® three times daily for several months. Another subject was treated with Kenalog® with no demonstrable improvement.

Case Report

A quarterback for a local professional football team presented early one Saturday morning with a severe pain in his right shoulder. There was no definitive history of injury. The forward flexion, abduction, internal rotation, external rotation, and extension were reduced to half normal

capacity with intense pain. Moderate joint tenderness was present. X-ray films taken from multiple projections were found to be normal.

While the patient was seated on the examining table, the DMSO solution later revealed to contain Kenalog® was applied to his shoulder. He fainted during the application, but quickly regained consciousness and noted that the shoulder pain had disappeared. Although my notes do not record whether his team won, he was able to participate fully in the football game scheduled that afternoon.

Conclusion

While the cases reported were studied some 18 years ago, it is likely that similar results would be

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HAVE YOU HEARD? . . .

A new independent network, MDTV, recently initiated a medical education series that will reach approximately 77 per cent of all US physicians. In Providence, the weekly programs are broadcast on WSMW (Channel 27) at 6 am Tuesdays. The initial programming includes two 30-minute segments, "Cardiology Today," and "Your Practice." The first program is aimed at providing primary care physicians with information regarding recent advances in cardiovascular medicine. "Your Practice" is a television magazine designed to assist physicians with managing their practices, professional relations, and finances. Specific topics to be covered include physician/patient relationships, medical technology, medical office management, health legislation, professional liability, investments, and estate and tax planning. Other programs will be added in April.

• • •

Clinical social workers may receive direct payments under the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), without having to be referred or supervised by physicians. CHAMPUS in 1980 began paying clinical social workers directly under an experimental program authorized by Congress. Before that time, supervision of their professional services by a physician was required under the program.

demonstrated if the clinical trials were repeated. As the contents of the bottles were concealed during the study, I was not able at the time to determine whether added substances were carried into the circulatory system. The comparative therapeutic effects of application of DMSO as augmented with cortisone and the unadulterated substance thus remain unknown.

Although it has been claimed that DMSO penetrates the circulatory system, there was no indication that it is capable of carrying with it such substances as steroids. The incidence of adverse reactions was the same for both substances. The use of DMSO in human subjects must be postponed until there is satisfactory evidence that no major ill effects will result from its extended use.

The Medical Products Division of the 3M Company has developed a portable neuromuscular stimulation system with electrodes designed specifically for muscle stimulation. Equally effective in stimulating both large and small muscle groups, the new Myocare Dual Channel Neuromuscular Stimulator Kit®, is appropriate for use in the home as well as in a clinical setting. The patient can be instructed to set a timer which automatically shuts off the system at the end of the session. Company officials claim that the unique design of the new product, compared to traditional electrodes, permits a more constant flow of current under the electrode and enhanced conformity to body contours. This should result in more "comfortable and efficient stimulation with no hot spots."

• • •

A surprisingly high number of complications may result from the utilization of lasers in microsurgical procedures, according to a paper in the January 1984 *Archives of Otolaryngology*. A survey of 229 otolaryngologists revealed approximately 80 complications resulting from the use of lasers. While many of the cited complications were not "serious," they emphasized the need for adequate training and knowledge before utilization of the new technology.

(Continued on page 138)

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Case Record: Rhode Island Hospital

Maurice M. Albala, MD
Tom J. Wachtel, MD
George F. Meissner, MD
Mark Fagan, MD, Editors

Presentation of Case

A 41-year-old white female was admitted for cardiac catheterization because of post-infarction angina. The chest x-ray film taken upon admission showed a right middle lobe infiltrate and a probable right hilar mass.

The patient presented with a history of cough productive of white sputum of several weeks' duration. She also complained of recent exertional dyspnea, malaise, anorexia with a 15 lb weight loss over two weeks, and night sweats during the previous three nights. She noted the presence of pleuritic pains in the upper mid-back and in both shoulders, which were distinct from previous exertional anterior chest pains. She denied hemoptysis, fever, chills, or a history of tuberculosis.

The past medical history included an anterior wall myocardial infarction three months prior to admission, followed by recurrent chest discomfort. She had a history of hypertension and heavy cigarette smoking. The results of a previous chest x-ray examination taken at another hospital three months prior to admission were not available. Medications upon admission included diltiazem, 60 mg three times daily, and sublingual nitroglycerin tablets, as necessary.

The physical examination revealed a rectal temperature of 101.8°F (38.8°C), blood pressure 95/65, heart rate 120, and respiratory rate 20. The patient was a pleasant, healthy-appearing white female who exhibited no signs of acute distress although she occasionally coughed during the examination. There was a 1x2 cm firm, slightly tender, non-fixed submandibular lymph node. No other adenopathy was noted. The chest was clear. The cardiac examination was normal, except for a two-component pericardial friction rub noted by one observer. There was no hepatosplenomegaly. The extremities revealed no clubbing, cyanosis, or edema. The neurological examination was within normal limits.

The laboratory results included a hemoglobin of 11.4 g with a hematocrit of 35 per cent and a mean cell volume of 93 μm^3 . The white blood count (WBC) was 9,400 with 88 per cent polymorphonuclear cells, 3 per cent lymphocytes, 5 per cent monocytes, 3 per cent eosinophils, and 1 per cent basophils. No toxic granulations or vacuoles were noted. The platelet count was 495,000. Sodium was 140, potassium 5.2, chloride 100, and bicarbonate 25 mEq/L. The blood sugar was 93, blood urea nitrogen 14, creatinine 0.9 mg/dL. The prothrombin activity was greater than 100 per cent, and the urinalysis was normal. The chest x-ray film revealed a large right hilar mass with associated volume loss and right middle lobe infiltrate. The arterial blood gases, taken with the patient breathing room air, showed a pH of 7.45; pO_2 of 62 mm Hg; pCO_2 of 38 mm Hg; and a bicarbonate of 26 mEq/L. The SGOT was 10; SGPT 6; LDH 383; CPK 27 IU/L; alkaline phosphatase 9.6 IU/dL; total bilirubin 0.2 mg/dL; calcium 9.0 mg/dL; phosphate 3.3 mg/dL; magnesium 1.6 mEq/L; total protein 6.9 g/dL; and albumin 3.3 g/dL. The erythrocyte sedimentation rate was 133 mm/hour. The serum iron was 12 mcg/dL and the iron binding 177 mcg/dL. The B_{12} and folate were normal.

Following admission, the patient received 500 mg of erythromycin by mouth every six hours and ferrous sulfate. The cough, back pain, and fever persisted, however, and the white blood count remained at 10,000 with a left shift.

Tomograms showed a large right hilar mass with a narrowing of the bronchus intermedius. The orifice of the right middle lobe could not be identified, and there was a peripheral parenchymal density. The left lung field appeared normal. Multiple blood, urine, and throat cultures were negative as was the sputum cytology.

On the seventh hospital day, a fiberoptic bronchoscopy revealed extrinsic compression of all

major right lobar bronchi. The mucosa of the right upper and lower lobe bronchi appeared normal. The opening of the right middle lobe bronchus was totally compressed, and mucosal irregularities and friability were evident. Biopsies obtained from the right middle lobe were consistent with nonspecific acute and chronic inflammation. No evidence of tumor was present. Bronchial washings from the right middle lobe revealed a single fragment of atypical epithelium. The washings were negative for acid fast bacillus (AFB).

On the tenth hospital day, the patient, after developing atrial flutter, hypotension, and chest pain, was transferred to the coronary intensive care unit. A dose of 2 mg dihydromorphine hydrochloride was administered intravenously (IV) to relieve the chest pain. After the patient was successfully cardioverted with 100 Joules, she was maintained on digoxin and quinidine sulfate. The cardiac enzymes were not elevated. Erythromycin was discontinued. Clindamycin, 600 mg intravenously every six hours, and gentamicin, 70 mg every eight hours after a 90 mg loading dose, were initiated.

On the eleventh hospital day, the patient complained of pleuritic chest pain. A lung scan showed a matched ventilation/perfusion defect proximal to the right middle lobe and a large perfusion defect in the right upper lobe, which was normally ventilated. The left lung field was normal.

There were no additional episodes of chest pain or arrhythmias, and the patient was returned to the medical unit on the twelfth hospital day. Her cough persisted and was productive of large amounts of sputum. She continued to spike daily temperatures, and indomethacin, 25 mg three times a day, was begun on the eighteenth hospital day. A bone scan was negative for lytic lesions, but demonstrated bilaterally enlarged kidneys.

On the twentieth hospital day, a diagnostic procedure was performed.

Differential Diagnosis

Allan D. Erickson, MD:* I should like to begin by reviewing the posterior-anterior (PA) and lateral chest roentgenograms to emphasize some difficulties in their evaluation.

While no mediastinal lymph node enlargement can be clearly identified on the PA and lateral

radiographs and on the tomogram, two suspicious areas deserve further comment. The area of the azygos node on the PA film seems generous. Since the medial margin along the right paratracheal stripe is sufficiently indistinct as to preclude measurement, the question of azygos lymphadenopathy must remain open. Similarly, the left hilar area appears plump on the PA film. If the lateral chest roentgenogram is examined carefully, a sharply margined tubular lucency appears to be emanating downward from the orifice of the left upper lobe bronchus. This probably represents the bronchus to the left lower lobe, or perhaps also the bronchus to the superior segment of the left lower lobe. These side views of airways are rarely seen on routine lateral films in the absence of lymphadenopathy.¹ Although mediastinal lymphadenopathy cannot be diagnosed with certainty, there remain at least two areas of possible involvement.

In general, the presence of bilateral hilar masses nearly always signifies the involvement of lymph nodes or blood vessels. The differential diagnosis of unilateral hilar mass must include two additional possibilities, a primary pathologic process appearing as a mass, eg, bronchogenic carcinoma; or a congenital lesion, eg, bronchogenic cyst.² I shall not comment on these possibilities further as the clinical course is not consistent with the presence of a bronchogenic cyst or other congenital lesion, nor does it support any of the diagnoses involving enlarged vasculature.

The differential diagnosis of unilateral lymph node enlargement consists of two major categories, infections and malignant tumors. Infectious causes include primary tuberculosis; histoplasmosis and other fungi; selected bacteria, such as those organisms causing tularemia; mycoplasma pneumonia and psittacosis; and also occasional viruses. In the absence of any exposure or travel history and because of the lack of response to erythromycin, several of these factors can easily be eliminated. Malignant tumors are the other major cause of unilateral hilar lymph node enlargement. The three principal diagnoses to consider include primary bronchogenic carcinoma, metastatic cancer, and lymphoma. While bilateral lymph node enlargement is associated with both metastatic cancer and lymphoma, there can be markedly asymmetric presentations or unilateral disease. Finally, sarcoidosis, a disease of unknown etiology, must also be considered in the differential diagnosis.

As it seems unlikely that the diagnosis can be established solely from the chest radiograph, let

* Assistant Professor of Medicine, Brown University Program in Medicine

us review the key features of the clinical history. This 41-year-old woman had coronary artery disease. Although there are diseases, eg, vasculitis, which might explain either premature atherogenesis or myocardial infarction without significant coronary artery disease, her past history of smoking and hypertension are sufficient to explain a second process, namely, coronary artery disease. She presented with a history of cough, dyspnea, anorexia, a substantial weight loss, fever, night sweats, and chest pains. In the hospital, daily fever occurred despite two separate courses of antibiotic therapy. The physical examination demonstrated a single submandibular lymph node and a pericardial friction rub. The labora-

Table 1. — Causes of Ventilation/Perfusion Mismatch on Lung Scan

Bronchogenic carcinoma
Other masses compressing vessels
—Metastatic cancer
—Lymphoma
—Sarcoid
Mediastinal fibrosis
—Histoplasmosis
—Radiation therapy
Emboli
—Tumor emboli
Vascular abnormalities
—Congenital pulmonary artery agenesis or stenosis
—Vasculitis
—Pulmonary artery hypertension

tory studies revealed anemia, hypoxemia, a markedly elevated erythrocyte sedimentation rate, and the described radiologic findings. Moreover, there was bronchoscopic evidence of bronchial compression with abnormal mucosa at the right middle lobe orifice, but without an endobronchial mass. A lung scan was abnormal, and the bone scan revealed bilateral renal enlargement. There are many causes of ventilation/perfusion mismatch on the lung scan other than pulmonary embolus, and Table 1 lists several of these.

The causes of bilaterally enlarged kidneys are displayed in Table 2. Although most are primary renal diseases with little chest involvement, such diagnoses as multiple myeloma, amyloidosis, and lymphoma cause chest roentgenographic abnormalities and must be considered. In a review of 958 cases of multiple myeloma from the Mayo Clinic, Kintzer and colleagues report on the types of intrathoracic involvement at the time of the initial diagnosis.³ Twenty-eight per cent of the

patients had typical osteolytic bone lesions, primarily in the ribs; 10 per cent had parenchymal infiltrates, although these were usually due to infections rather than the malignant process itself; and eight per cent presented with plasmacytomas, most of which were intimately involved with the ribs. Only 11 patients had a pulmonary plasmacytoma without any bone involvement, and only two of those were in the hilar region. An osteolytic rib lesion associated with a soft tissue mass protruding into the thorax should strongly suggest multiple myeloma. The absence of typical chest radiographic findings, however, and the lack of bone pain, skeletal abnormalities, and proteinuria weigh against multiple myeloma in this case. Amyloidosis usually presents as a nodular or diffuse interstitial disease on chest roentgenogram, and lymph node

Table 2. — Causes of Bilateral Renal Enlargement

Polycystic disease
Acute glomerulonephritis
Acute pyelonephritis
Systemic lupus erythematosus
Bilateral hydronephrosis
Acute tubular necrosis
Multiple myeloma
Amyloidosis
Leukemia
Lymphoma
Acromegaly
Medullary sponge kidney
Bilateral renal vein thrombosis

involvement is rare. Amyloid in the lung is usually of primary variety, and this patient would be unusually young for that condition. I shall return to the possibility of lymphoma later.

Primary tuberculosis is probably the most common infectious disease to produce radiographic abnormalities. As Kahn pointed out in 1977, the clinical and roentgenographic spectrum of tuberculosis (TB) has changed slightly as primary tuberculosis apparently is becoming more prevalent in adults.⁴ In a report on 88 patients at Boston City Hospital, five had unilateral hilar lymph node disease similar to that of our patient. Dhand reported on a series of adult patients with intrathoracic TB adenopathy in 1979.⁵ While 25 of 33 patients revealed evidence of paratracheal lymph node disease, unilateral hilar lymphadenopathy was present in 15 of them. Since all patients who were tuberculin skin tested were found to be positive, a negative skin test would have been strong evidence against a diagnosis of TB for this patient. Although histoplasmosis is

the fungal disease most commonly associated with exuberant mediastinal or hilar lymph node response, it seems unlikely in the absence of significant travel history.

The last disease other than a malignant tumor to be considered in this patient is sarcoidosis. Hilar lymph node enlargement is seen in most sarcoid patients, and in one series, lymph node enlargement was the sole abnormality in 43 per cent of patients at the time of the initial diagnosis.⁶ While hilar, paratracheal, and other lymph node groups are commonly involved, bilateral hilar adenopathy is present in nearly all cases. In a Mayo Clinic series of 800 patients with confirmed diagnoses, only 38 (8 per cent) of 472 cases with lymph node disease demonstrated unilateral lymph node enlargement on the initial chest radiograph.⁷ Sarcoidal lymph nodes have been reported occasionally as compressing bronchi and even pulmonary arteries, but this rarely occurs. Winterbauer states that patients with asymptomatic bilateral hilar lymphadenopathy have sarcoidosis and that symptomatic patients with unilateral hilar adenopathy have lymphoma.⁸

Bronchogenic carcinoma is certainly a significant diagnosis to consider in this patient. As the incidence of lung cancer in women has increased dramatically in recent years, the patient unfortunately is not too young for such a diagnosis. She had a history of heavy smoking. The chest roentgenogram, bronchoscopic findings, lung scan findings, and many of the symptoms are perfectly consistent with bronchogenic carcinoma of, for example, the small-cell histological type. Persistent and unresponsive fever and night sweats, however, are unusual in the sole presence of lung cancer. Most patients with lung cancer have fever because of an obstructing pneumonia. Since the organisms causing these pneumonias are typically sensitive to antibiotic therapy, the treatment with erythromycin should have caused the temperature to return to normal. Moreover, the presence of bronchogenic carcinoma does not explain the bilateral renal enlargement. Although patients who die from bronchogenic carcinoma with metastases have renal involvement in 20 to 30 per cent of autopsied cases, these renal metastases appear as a single or multiple defects rather than as bilateral renal enlargement on a scan.

It is not necessary to consider other primary lung tumors in this patient, although alveolar cell carcinoma, which has been reported in young patients, should be mentioned. While the chest

radiographic presentation of this cancer varies considerably, the presence of hilar lymph node involvement is distinctly unusual. In a series reported in 1973, only one of 29 cases demonstrated involvement of the hilar lymph nodes.¹⁰ An entity known as giant cell carcinoma is interesting in view of the very rapid course of the mass lesion in our patient, but the chest roentgenographic findings are not typical of this cancer.

Another malignant disease to consider in this case is metastatic cancer from a nonpulmonary site. While the protocol does not indicate a probable primary site, it is important to rule out such entities as renal cell carcinoma. Between 30 and 40 per cent of patients with metastatic renal cell carcinoma have no symptoms related to the kidneys.¹¹ The classic triad of hematuria, flank pain, and an abdominal mass is present only in 10 to 15 per cent of patients. The chest radiograph may present such varied forms as solitary or multiple pulmonary nodules or masses, hilar or mediastinal lymph node enlargement with or without associated parenchymal disease, bone involvement, the comparatively rare lymphangitic carcinomatosis, and endobronchial metastases. Involvement of the lungs frequently occurs in the course of renal cell carcinoma because of the several pathways available for metastatic spread from the kidneys, including hematogenous routes through the inferior vena cava, lymphatic routes to lymph nodes and the thoracic duct, and Batson's plexus, a series of valveless perivertebral veins which connect to intercostal and bronchial veins. However, no specific signs, especially the non-renal abnormalities so characteristic of renal cell carcinoma, suggest this disease. The presence of hypercalcemia, elevations of the alkaline phosphatase or erythrocytosis, and bilateral renal enlargement would be distinctly unusual.

The diagnosis of lymphoma must be considered because its presence would explain such features of this case as the chest radiograph, the classic "B" symptoms of fever and weight loss, the lung scan, and the bilateral renal involvement. Also, renal abnormalities may be produced in such patients by other mechanisms, including renal stones, infection, and ureteral obstruction secondary to abdominal lymph node enlargement. Intrathoracic involvement by metastases is quite common. In some series up to 90 per cent of patients demonstrate intrathoracic involvement at some point. Blank reported from Stanford University in 1980 on a series of 165 consecutive patients with Hodgkin's disease who had been

diagnosed during the early 1970s.¹² Sixty-seven per cent of the patients exhibited intrathoracic involvement at the time of initial presentation, and all but one had hilar or mediastinal lymph node enlargement.

As the most common intrathoracic abnormality, lymph node enlargement can involve several nodal groups, especially the paratracheal lymph nodes. Although anterior mediastinal lymph nodes, best seen on lateral film, are present in relatively few cases, they offer an important differential feature from sarcoidosis. Sarcoidosis rarely involves the anterior mediastinal compartment. Furthermore, these nodes can occasionally erode into the sternum, a finding very suggestive of lymphoma. While two-thirds of patients with hilar lymph node enlargement have bilateral involvement, asymmetry is common. Subcranial nodes and nodes in the cardiophrenic angles may also be seen. It is important to examine them specifically, since such nodes frequently masquerade as "fat pads" and may be overlooked during a casual examination of the chest roentgenogram. In the absence of detectable mediastinal lymph node involvement, hilar lymph node enlargement was unusual in the series described by Blank. If this patient has no mediastinal lymph node enlargement, this certainly would be an important point against that diagnosis. Twelve per cent of the patients in this series had associated parenchymal disease including either single or multiple nodules, infiltrates, and diffuse reticulonodular disease. Pleural effusions and bone involvement were uncommon during the initial stages of the disease. Although most patients with lymphoma have clinical signs of peripheral lymphadenopathy, only five to 10 per cent reveal hilar or mediastinal lymph node enlargement in the absence of superficial lymph node enlargement. The symptoms seen in the patient are all very typical of lymphoma. The diagnosis can occasionally be made through a brush biopsy at the time of the fiberoptic bronchoscopy,¹³ and even sputum cytology diagnostic of the condition has been reported.¹⁴

Lymphoma is the single disease which best explains the abnormalities present in this patient. I would have recommended a mediastinoscopy, or possibly a limited thoracotomy. I would predict the confirmation of a malignant process.

Doctor Erickson's Diagnosis

Lymphoma

Mediastinal involvement

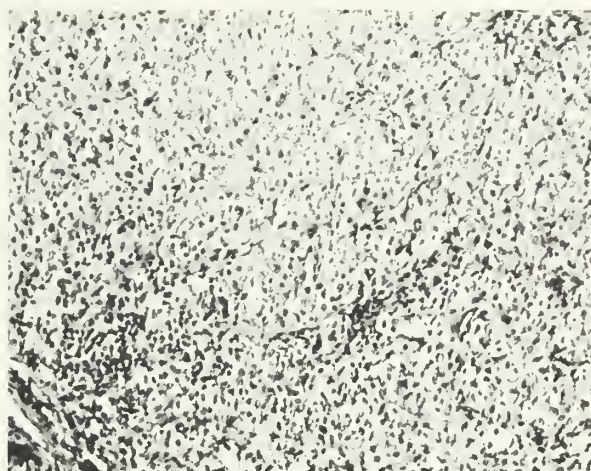


Fig 1. Malignant lymphoma histiocytic type. Note clusters of small lymphocytes in lower left for comparison.

Pathological Discussion

George F. Meissner, MD:* At mediastinoscopy, a tumor was found to be composed predominantly of large, histiocyte-like cells, consistent with malignant lymphoma, large cell type (Fig 1). A number of immunohistochemical stains were performed on paraffin-fixed material (keratin, carcinoembryonic antigen, alpha-fetoprotein, IgA, IgG, IgM, albumin, alpha-1-antitrypsin) and revealed no marker characteristic of a specific cell type. No fresh material was available for B and T lymphocyte typing. A reticulum stain was equivocal as was an electron microscopic study.

The patient died several days after the procedure in cardiogenic shock suspicious of posterior wall infarction. The autopsy confirmed the presence of arteriosclerotic cardiac disease with healed, healing, and terminal posterior wall infarction. There was extensive malignant lymphoma involving the mediastinal and paraortic lymph nodes and nearly all the organs. Multiple 1-2 cm nodules of tumor were present in the lungs, spleen, adrenal glands, kidneys, ovaries, thyroid, and alimentary tract. A small nodule of lymphoma was found epicardially at the cardiac apex. The liver was free of tumor.

The tumor cells were identical in all sites to the biopsy material. Large cell lymphomas, although labeled histiocytic under the Rappaport classification system, rarely appear as truly histiocytic in origin. Most are B lymphocytes, and a few are T lymphocytes. The exact origin was, however, not determined in this case.

The cardiac involvement was incidental and

*Pathologist-in-Chief, Rhode Island Hospital

occurs in 20 per cent of patients with advanced malignant lymphomas.¹⁵ The mechanism of death, however, was due to myocardial infarction.

Pathological Diagnosis

Large cell "histiocytic" lymphoma with extensive involvement of lymph nodes, spleen, lungs, adrenal glands, kidneys, ovaries, thyroid, and heart

Arteriosclerotic heart disease with healing and terminal posterior wall infarction

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Radiographic Diagnosis of Intramuscular Lipoma

Sidney Pollack, MD
Alan D. Steinfeld, MD

A 68-year-old woman complained of the sudden appearance of a swelling on the central surface of her right forearm. Eleven years earlier a hysterectomy for a carcinoma of the endometrium had been performed. Seven years after surgery, the tumor recurred in the vagina and was successfully treated with radiation.

A lateral xerogram revealed an elliptical, low density lesion, approximately 4 cm in length, deep in the anterior soft tissues of the right forearm (Fig 1). There was concomitant swelling of the overlying soft tissues.

Based on the radiographic findings, a diagnosis of intramuscular lipoma was made. Concern over the possible metastasis of the tumor led to an excisional biopsy. Histological examination of the specimen showed a typical lipoma.

Discussion

If the tumor is superficial and located in such typical locations as the trunk, neck, or proximal portions of the extremities, the diagnosis of lipoma can generally be made on clinical grounds. In approximately 10 per cent of cases, lipomata are at or distal to the elbow and in only one per cent do they lie deep within the body.¹ When a deep-seated lipoma is suspected, or when there is cause to suspect another etiology for a mass in the extremity, radiographic confirmation may be desirable. Xeroradiography provides an excellent means for evaluating these tumors.

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Fig 1. Lateral xerogram of right forearm. Note low density, deep seated mass.

The typical lipoma is a subcutaneous collection of fibroadipose tissue which may or may not be encapsulated. Paget first described such a lesion in 1853.² The tumors may be inter- or intramuscular and present as a fixed, soft tissue mass. On histological examination, a predominance of blood vessels and connective tissue may lead to the diagnosis of infiltrating intramuscular lipoma.^{3, 4} Such tumors do not undergo malignant transformation but can recur locally if not completely excised.

A radiological assessment can obviate the need for surgery. If, as in this patient, the clinical situation makes histologic confirmation necessary, the extent of the lesion can be confirmed prior to surgery by radiographic examination. Chew and colleagues describe 10 patients with intramuscular lipoma where the preoperative radiographic evaluation consisted of plain radiography, xeroradiography, bone scintigraphy, angiography, computed tomography, and sonography. It was found that although plain radiography, xero-

radiography, and bone scintigraphy may be utilized to detect or exclude bone involvement, these modalities do not provide anatomic delineation. While angiography reveals the vascular anatomy, these tumors can extend beyond their vascular supply. Chew concludes that computed tomography provides the most efficacious means of defining the anatomic extent of these lesions.⁵

Ness and colleagues used xerography in the evaluation of 67 patients with lipoblastic tumors of the soft tissue. Included were 18 cases of liposarcoma, 37 cases of lipoma, and 12 "mixed" cases of fibrolipomas and reticular lipoma. In this series, xeroradiography improved the visibility of

soft tissues over film radiography in 20 out of the 23 cases in which both modalities were used. On xerographic examination, lipomas were found to be radiolucent, rounded, or regular masses. Liposarcomas, in contrast, were radiopaque, irregular, and infiltrative lesions.⁶

Conclusion

Deep-seated, apparently fixed masses can be evaluated quickly and accurately with xeroradiography. The finding of a rounded, regular, radiolucent mass with fat density, as in this case, strongly suggests a deep-seated or infiltrating lipoma.

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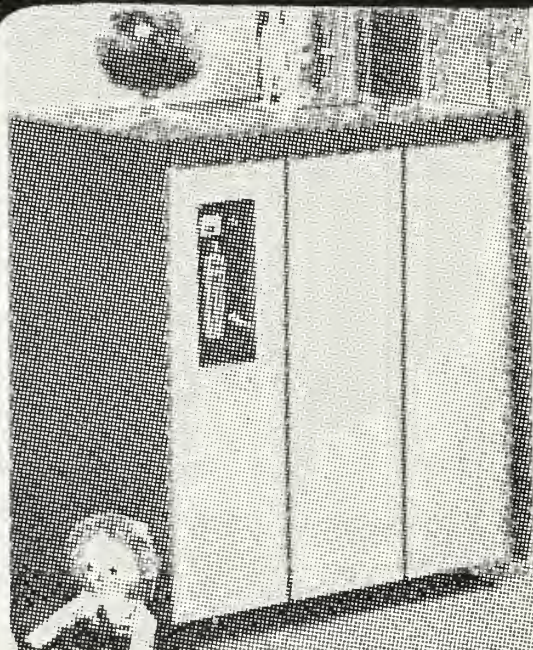
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Rhode Island Health Plan Implementation Priorities

A Mutual Commitment to Improve Health Care in Rhode Island Should Be Our Goal

Joseph E. Caruolo, MD
Beverly E. Freedman, MEd
William J. Waters, PhD

The National Health Planning and Resources Development Act of 1974 (PL 93-641) mandated a framework for the process of health planning with each state. The law requires participation by the public as part of the process.¹ In Rhode Island, the Statewide Health Coordinating Council (SHCC), which includes 30 volunteer consumers and providers of health care appointed by the governor, serves as the medium of the health planning effort. Working through a public forum, the SHCC evaluates and plans for the health care needs of the state, monitors and responds to rising health care costs, and works to improve the delivery of services.

The process of health planning implies recognition of the fact that the current allocation of resources does not always reflect national and local priorities. Through the development of the state health plan, this allocation is carefully reviewed.

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Development of the State Health Plan

Development of the second state health plan was initiated in September 1980. At that time, input was solicited from the general public, including some 188 "consultant organizations" which were selected because of their interest or expertise in areas related to the plan. During the next two years, the Council worked to develop a draft document. While the plan was being developed, the first 30 minutes of each Council meeting were devoted to public testimony. Written comments also were welcome.

In November 1982, the Council tentatively approved the second state health plan. The draft was the subject of public hearings in Providence, North Kingstown, and Woonsocket. Many of the recommendations made during the hearings were included during the revision process, and in January 1983 the final document was forwarded to the governor for his review. After gubernatorial approval was received two months later, the document was forwarded to the US Department of Health and Human Services.²

The overall purpose of the plan is to develop a reasonable, affordable strategy for funding both existing and proposed health services, agencies, and programs. To accomplish this goal, the plan attempts to restrain the rate of cost increases for inpatient and nursing home utilization so that the public can afford to invest proportionately more health dollars in preventive services and in such treatment alternatives as primary care, community mental health services, home care, day care, and hospice care. The plan also emphasizes the importance of providing more information to consumers on the appropriate utilization and costs of health care services. By seeking changes

Table 1. — Rhode Island State Health Plan: Health System Interventions

STRATEGY	ACTION
Community health prevention programs	Penalties for drinking and driving Mandatory seat belt use Avoid cigarette and alcoholic beverage advertisements directed to children Occupational disease studies
Create financial incentives to promote healthier behavior	Raise excise taxes on cigarette and alcoholic beverages Lower insurance premiums for nonsmokers
Health information and education	School health education Coordinate health behavior information Worksite health promotion programs
Patient education and self care	Patient education in hospitals Promote self care
Improve patient and consumer information	Provide copies of hospital bills to patients and physicians Merge hospital charge and utilization data Provide the public with valid comparisons of hospital quality Publish information on variation in hospital use by place of residence Information about practices of physicians Physician acceptance of insurance reimbursement
Balance supply of acute care services with need	Surgical waiting lists and ambulatory surgery Study emergency room utilization Balance supply of acute care services with need Promote integrated systems of care Promote better integrated utilization review programs Promote regionalized perinatal health network
Reduce unnecessary long-term institutionalization	Match supply of nursing home beds with requirements Preadmission screening of applicants to nursing homes Create a social/health maintenance organization
Rationalize reimbursement practices	Raise fees for unspecialized services Limit hospital capital expenditures Pay real hospital costs Prospective reimbursement program to attain plan goals Include Medicare in prospective reimbursement Develop protocols for certain surgical procedures Study copayments for hospital care Educate physicians about costs of care
Appropriate integration of community health services	Plan service integration Fund integrated community mental health and substance abuse services Attend to immediate problems of constituent agencies Develop health centers plan
Expand scope and depth of health insurance coverage	Insure preventive services and alternatives to institutionalization
Increase the accessibility and continuity of health insurance	Offer employees group plan insurance
Balance health manpower supplies and requirements	Focus state support for medical education on needed specialties Encourage labor force participation of nurses

in the reimbursement system, the plan attempts to reward effective and efficient service delivery.

It is the goal of health planners not only to develop a technically feasible plan, but also one that is credible, practical, and appropriate for the community. These characteristics of the plan are essential to its next phase, implementation of recommendations.

Plan Implementation Priorities

In addition to the mandate to develop a state health plan, a critical responsibility for implementation also exists. While successful implementation depends on the voluntary commitment of the community, the Statewide Health Coordinating Council, as the author of the plan, bears considerable responsibility for its implementation.

Because of the voluntary nature of the SHCC and its limited resources, it could not work actively to implement all of the the 42 actions recommended by the state health plan (Table 1). The Council voted to select five recommendations as high priority items for its direct and active involvement.

To aid in its selection of the five implementation priorities, the SHCC conducted a community survey of the 188 consultant organizations, each of which was requested to select its most important five priorities from Table 1. Sixty-eight organizations, or 36 per cent, responded, including such key groups as the Rhode Island Medical Society, Hospital Association of Rhode Island, various state departments, and community hospitals. The Council members reviewed these survey results during the selection process.

To select the five implementation targets, SHCC members participated in a priority-setting process known as the "nominal group technique."³ The process consisted of two stages. During the first stage, each Council member was asked to select the one implementation step regarded as the most significant of the 42 recommendations. These were compiled and used as the basis for the next stage. Each member was then asked to select five implementation priorities from the list generated during the initial stage (Table 2).

Through the process, the Council selected five items to address actively during the next year: *promote school health education; promote self-care; balance the supply of acute care services with their need; promote integrated systems of care; and insure preventive services and alternatives to institutionalization.*

The recommendation on school health educa-

Table 2. — Results of the Nominal Group Technique: First Round Selection by SHCC Members of Implementation Priorities

—Occupational disease studies
—School health education
—Worksite health promotion program
—Patient education in hospitals
—Promote self care
—Provide public with valid comparisons of hospital quality
—Balance supply of acute care services with need
—Promote integrated systems of care (ie, HMOs and networks)
—Limit hospital capital expenditures
—Fund integrated community mental health and substance abuse services
—Develop protocols for certain surgical procedures
—Insure preventive services and alternatives to institutionalization
—Focus state support for medical school education on needed specialties

tion calls for a comprehensive school health education program for grades kindergarten through twelve for all Rhode Island schools, as originally proposed in a report of the State Health Education Study Committee.⁴ It was suggested that the Center for School Health Education, based within the Department of Education, should foster this effort, primarily by providing assistance of methods and materials to the local school districts.² (p 333)

The concept of self-care, within the context of the state health plan, does not emphasize self-diagnosis and treatment. Instead, it focuses on expanding the ability of the consumer to use the health care system more effectively. The recommendation also calls for the evaluation and distribution of materials to promote the rational utilization of existing resources.² (p 345)

As for the third priority, the supply and demand for acute care services, the plan recommends that the supply of acute care hospital beds should correspond to the objective medical requirements of the state and stresses the importance of developing alternate community-based services in both acute and long-term care systems.² (p 365)

The fourth recommendation, integrated systems of care, involves encouragement of continuous and cost-effective delivery of health services by promoting such integrated systems of care as health maintenance organizations and regional health service networks. The plan advocates the development of a pilot program to evaluate the effectiveness of a regional health service network for a target population and recommends

that the Department of Social and Rehabilitative Services expand the number of Medicaid recipients who are enrolled in HMOs.² (p 373)

In the final implementation priority, preventive services and alternatives to institutionalization, it is recommended that all third-party payers expand their basic health insurance plans to cover such preventive services and alternatives to institutional care as outpatient mental health services, home health services, adult day care, hospice treatment, and day hospital care for the elderly. The controlled and prudent introduction of cost-effective benefit packages is also encouraged.² (p 418)

Implementation Process

To address these priority recommendations effectively, the Council decided to establish five task forces. Each SHCC member was assigned to a task force. The task forces will function for one year, with the final report from each group due by June 30. While the voting membership of each task force will consist of the appointed SHCC members, non-voting "consultants" will be asked to serve, allowing the Council to benefit from existing expertise and experience within the community.

Each task force will select implementation strategies consistent with the nature of the priority statement. Potential roles for the task forces include those of convener, catalyst, community organizer, advocate, drafter of legislation, provider of information, lobbyist, and so forth. After review by the SHCC Implementation Committee, the strategies developed by the task force will be submitted to the full Council for approval.

Summary

The true test of good planning is its implementation. The Council is aware of this fact, and it has initiated, carried out, and evaluated the first im-

plementation cycle following adoption of the first state health plan in 1980 and the annual implementation plan in 1981. Although less focused than the current implementation cycle, these first efforts proved to be significant, often affecting the health care system in positive ways. The recent evaluation of implementation initiatives, in fact, reviews the progress in each category recommended by the Council. The report concludes that, as a result of both SHCC and community-wide activities, much constructive change has occurred.⁵

During the current implementation cycle, the SHCC again expects to work closely with the community, especially on the five selected priorities. At the same time, the Council will also seek ways to implement the remaining actions in the health plan.

Planning is the first and, in many ways, the easiest step. The SHCC seeks the assistance from the community to assure that the state health plan does not lie dormant. Our mutual commitment to improve health care in Rhode Island should be our guide as we address implementation of the health plan.

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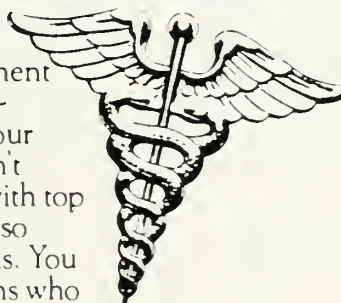
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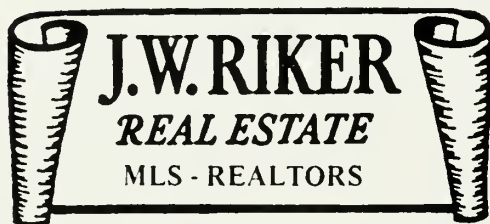
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Brentwood Instruments, a California distributor of cardiac instruments, has introduced an automatic electrocardiograph system which is "no bigger than a textbook and weighs less than four pounds." The Cardimax FX-102® operates from either standard power or a rechargeable power pack. Operation is by touch-sensitive key pads which calibrate the system, position the stylus, adjust the sensitivity, and automatically switch through a 12-lead examination. The recording length for each lead is selectable, from one to ten seconds per lead.

• • •

While most Americans have access to a regular source of general medical care, more than 28 million persons, or 12 per cent, reported difficulties in obtaining necessary medical treatment, according to a study recently released by the Robert Wood Johnson Foundation. Moreover, most Americans see themselves as "healthy," but more than one-third believe that the delivery system itself is "sick."

The report, based on a 1982 survey of 6,600 households, suggests that the trend of improved access to basic medical care has continued since a previous national study in 1976. The rates of physician visits and hospital admissions have increased substantially for low-income Americans, especially since the introduction of Medicare and Medicaid in 1965. Five population groups, however, continue to have the greatest problems in obtaining medical care: the poor, the uninsured, and those in families where the head of the household is unemployed, not in the labor force, or did not graduate from high school. One million families reported that at least one member was refused care last year for financial reasons, including members of some 208,000 uninsured

families. On many indices of access to medical care, the study concludes that black Americans are "worse off than the national averages." They are significantly more dissatisfied with management of medical emergencies, and they rate their own health status less favorably than do whites in comparable income and age categories. In addition, nearly 20 per cent of Hispanic adults rate themselves as "being in serious trouble" using an index of health status indicators.

• • •

A new pediatric hospital in Vancouver, British Columbia uses teddy bears to show its small patients what will happen during nuclear imaging diagnostic procedures. Children's Hospital, currently the only pediatric facility in the Canadian province, serves as a referral center, and its patients often are transported by plane from their homes. Parents are encouraged to remain with their children during the radiological examination. Either a physician or a technician outlines the planned procedure to the parents, who in turn explain it to the young patient. The teddy bear is used to demonstrate how the mounted camera works. Before the hospital opened in July 1983, pediatric patients were sent to Vancouver General Hospital for diagnostic imaging procedures.

• • •

Diagnostic criteria now utilized to identify schizophrenic patients show a high degree of diagnostic consistency over many years, according to a report in the December 1983 issue of *Archives of General Psychiatry*. Researchers at the Washington University (St. Louis) Psychiatry Clinic, in a study of 500 patients over a 14-year period, also found that the criteria select cases with a marked excess of probable schizophrenia among their relatives.

• • •

Men with an extra male factor in their genetic code are not necessarily destined to be more aggressive than males with normal codes, according to a report in the January 1984 issue of *Archives of General Psychiatry*. This finding, based on a controlled study of nearly 4,600 men, conflicts with studies of incarcerated men which show that males possessing an additional Y chromosome display a greater predisposition to violence. Researchers from the Mount Sinai School of Medicine in New York concluded that, while a positive correlation between testosterone levels in men



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and criminal behavior exists, there is no evidence that "the hormone is a mediating factor in criminal behavior" of men with an extra chromosome.

• • •

Health Information Systems, Inc. (HIS), a supplier of computerized software for physicians and hospitals, has announced the development of its Materials Management System,[®] a software package for the accurate and efficient tracking of inventory items. The new software is designed for use on IBM mainframe computers and is fully integrated with such other systems as the HIS Accounts Payable and General Ledger. The new program is intended to help hospitals utilize supplies more effectively by permitting the creating, editing, and canceling of purchase orders and the tracking of all inventory items.

• • •

Accidents are the major cause of deaths in children, one to 14 years old, with fires, suffocation, and drowning as the primary factors. The January 1984 issue of the *American Journal of Diseases of Children* presents an overview of such causes of childhood accidents as burns, strangulation and asphyxiation, drowning, falls, firearms, poisoning, and unsafe toys, and considers what parents can do to prevent accidents. Such passive measures as child-resistant drug packaging apparently are more effective in preventing injuries than safety education programs.

• • •

Many studies of antibiotic therapy that physicians depend on for clinical guidance are so poorly performed that their value may be questionable, according to a report in the January 1984 issue of *Archives of Surgery*. British researchers found that as many as 40 to 45 studies under review contained serious deficiencies in one or more areas, including defects in design, ethical errors, inappropriate statistical analysis, and misleading presentation of data.

• • •

According to a paper in the December 1983 *Archives of Surgery*, radionuclide angiography is a highly sensitive method for determining heart function following blunt chest injuries, such as those sustained in automobile accidents. In a prospective study of 35 patients, Doctor Daniel P. Harley of the Los Angeles County Harbor/UCLA Medical Center found that electrocardiogram abnormalities were detected in eight patients

while radionuclide angiography abnormalities were seen in 26 patients. The researchers call for further study to evaluate the long-term care prognosis of such patients.

• • •

The use of antibiotics as animal feed additives does not pose a threat to human health, according to a recent report from the American Council on Science and Health. Moreover, the independent national scientific organization concluded that consumers would pay substantially more for meat and poultry if the use of antibiotics in livestock and poultry feeds were prohibited. While low doses of antibiotics have been added to animal feeds for more than 30 years, apparently with no reported human health problems, the Food and Drug Administration (FDA) recently proposed banning most uses of penicillin and tetracycline for this purpose. Congress has prohibited action by the FDA, however, pending the accumulation of additional scientific evidence against the practice. The Council has recommended that the health impact of the use of antibiotics in animal agriculture be subject to periodic

reevaluation to "determine if conditions have changed which might lead to a significant hazard in the future."

• • •

According to a report in the January 1984 issue of the *American Journal of Diseases of Children*, children who undergo continuous ambulatory peritoneal dialysis (CAPD) for kidney failure grow as fast as children being treated with hemodialysis. Children on CAPD also demonstrated improvement of renal osteodystrophy, a spectrum of abnormalities of bone growth associated with chronic kidney disease, when compared to children on hemodialysis. Researchers at the University of Florida College of Medicine report that the factors responsible for the growth retardation of children treated with hemodialysis remain speculative.

• • •

The Sequoia-Turner Corporation, a California-based manufacturer of laboratory instruments, recently introduced a compact, ionselective electrode analyzer which measures potassium in less than 30 seconds.

A WORD TO THE WHYS

WHY AMA? The AMA can help you build and improve the efficiency of your practice through Practice Management seminars and audio visual courses. These programs are designed to assist you in every phase of your practice by providing you with practical information about business procedures and management techniques. Practice Management: it's one more good reason why you should be part of the AMA.

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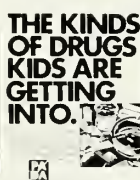
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BRIEF SUMMARY

PROCARDIA® (nifedipine) CAPSULES

For Oral Use

INDICATIONS AND USAGE: 1. **Vasospastic Angina:** PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation; 2) angina or coronary artery spasm provoked by ergonovine; or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

2. **Chronic Stable Angina (Classical Effort-Associated Angina):** PROCARDIA is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort-associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance but confirmation of sustained effectiveness and evaluation of long term safety in those patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS: Known hypersensitivity reaction to PROCARDIA.

WARNINGS: **Excessive Hypotension:** Although in most patients the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose fentanyl anesthesia. The interaction with high dose fentanyl appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of fentanyl, or other surgical procedures, or with other narcotic analgesics cannot be ruled out. In PROCARDIA treated patients where surgery using high dose fentanyl anesthesia is contemplated, the physician should be aware of these potential problems and if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery.

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients usually receiving a beta blocker have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: **General Hypotension:** Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug Interactions: Beta-adrenergic blocking agents. (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta blocking agents is usually well tolerated, but there have been occasional literature reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long-acting nitrates. PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis. Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Carcinogenesis, mutagenesis, impairment of fertility. When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy. Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients; transient hypotension in about 5%; palpitation in about 2%; and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication. Additionally, the following have been reported: muscle cramps, nervousness, dyspnea, nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LDH, SGOT and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature.

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine. PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x101) (NDC 0069-2600-41). The capsules should be protected from light and moisture and stored at controlled room temperature 59° to 77°F (15° to 25°C) in the manufacturer's original container.

More detailed professional information available on request.

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* Procordia is indicated for the management of:

- 1) Confirmed vasospastic angina
- 2) Angina where the clinical presentation suggests a possible vasospastic component
- 3) Chronic stable angina without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or nitrates or who cannot tolerate these agents. In chronic stable angina (effort-associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks' duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in these patients is not complete.

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References: 1. Kales A et al: *J Clin Pharmacol* 17:207-213, Apr 1977 and data on file, Hoffmann-La Roche Inc., Nutley, NJ. 2. Kales A: Data on file, Hoffmann-La Roche Inc., Nutley, NJ. 3. Zimmerman AM. *Curr Ther Res* 13:18-22, Jan 1971. 4. Kales A et al: *JAMA* 241:1692-1695, Apr 20, 1979. 5. Kales A, Scharf MB, Kales JD: *Science* 201:1039-1041, Sep 15, 1978. 6. Kales A et al: *Clin Pharmacol Ther* 19:576-583, May 1976. 7. Kales A, Kales JD: *Pharmacol Physicians* 4:1-6, Sep 1970. 8. Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. 9. Dement WC et al: *Behav Med* 5:25-31, Oct 1978. 10. Vogel GW: Data on file, Hoffmann-La Roche Inc., Nutley, NJ. 11. Karacan I, Williams RL, Smith JR: The

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Contraindications: Known hypersensitivity to flurazepam HCl; pregnancy. Benzodiazepines may cause fetal damage when administered during pregnancy. Several studies suggest an increased risk of congenital malformations associated with benzodiazepine use during the first trimester. Warn patients of the potential risks to the fetus should the possibility of becoming pregnant exist while receiving flurazepam. Instruct patient to discontinue drug prior to becoming pregnant. Consider the possibility of pregnancy prior to instituting therapy.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. **Adults:** 30 mg usual dosage; 15 mg may suffice in some patients. **Elderly or debilitated patients:** 15 mg recommended initially until response is determined.

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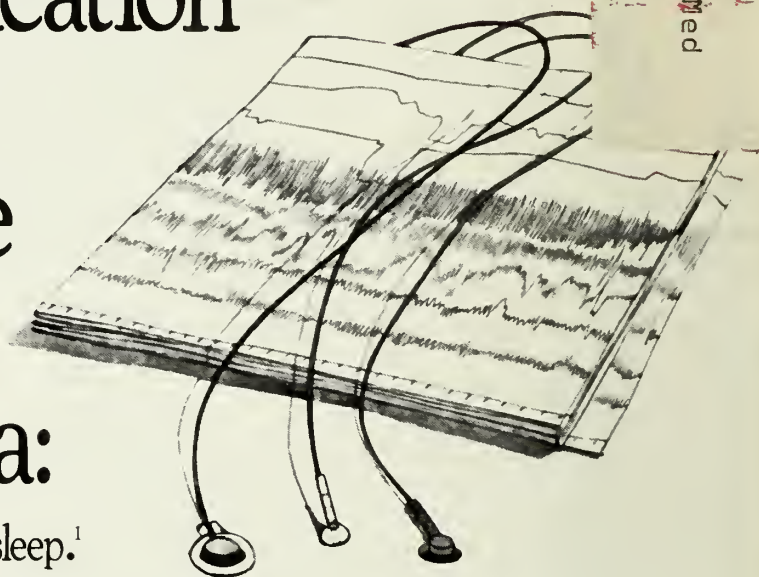
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Medical Journal

DISPLAY
SHELVES

For more on traffic
accidents in Rhode
Island, see page 157



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RADIOGRAPHIC CASE OF THE MONTH

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Newsletter

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March 1984

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PHYSICIAN GUIDE NOW AVAILABLE

At an April 5 press conference, Governor J. Joseph Garrahy announced publication of the Guide to Physician Services by the Rhode Island Medical Society.

Authorized by the House of Delegates in January 1983, the Guide is designed to help patients select the physician most appropriate for their needs. More than 850 RIMS members and 40 members of the RI Society of Osteopathic Physicians & Surgeons voluntarily participated in the project. Blue Cross & Blue Shield of Rhode Island underwrote the printing and distribution costs.

The 116-page Guide includes detailed information on the educational backgrounds and practices of RIMS members, including such items as hospital affiliations; specialty and subspecialty; type of practice; and office policies toward Medicare, Medicaid, and other third-party programs. It also contains two useful indices, one listing physicians by specialty and community and the other by foreign languages. It has been endorsed by the Department of Elderly Affairs, the Governor's Advisory Committee on the Aging, the Health Subcommittee of the Governor's Advisory Committee, the RI Consumers' Council, and the RI Society of Osteopathic Physicians & Surgeons.

The Guide has been mailed to all Society members. Copies also are available free of charge to the general public after April 15 through the public library system, 76 senior citizens centers affiliated with the Department of Elderly Affairs, RI Consumers' Council, and Governor's Citizens Information Service. Individual copies will not be available to the public at the Society's offices.

SOCIETY SEEKS MALPRACTICE REFORM

The Rhode Island Medical Society successfully introduced into the General Assembly a package of five bills intended to alleviate the escalating malpractice crisis. Sponsored by Sen John Revens (D., Warwick), the following bills have been assigned to the Senate Judiciary Committee:

- S 680 would establish guidelines for the courts to order structured payments of all awards greater than \$100,000. If enacted, the law would require such awards to be paid in monthly installments to "provide the plaintiff with a life-time income" instead of a lump sum payment.
- S 693 would reduce the interest on judgments from the current 12 per cent to 10 per cent annually. It also would shorten the period for the accumulation of interest from the date of the incident to the date the claim for damages was filed.
- S 698 would amend the collateral source rule. Under current judicial procedures, the defendant in a malpractice action may introduce as evidence any insurance or disability payments made to the plaintiff as a result of the injury. S 698 would require the courts to consider "changes in the marital, financial, or other status" of the plaintiff in determining the size of the award.
- S 708 would establish qualifications for expert witnesses in malpractice actions by requiring that the witness hold board certification in the appropriate medical specialty and demonstrate "personal experience and practical familiarity with either the practice or teaching" of the issue under litigation.
- S 709 would limit awards for "pain

and suffering to \$250,000.

To encourage membership support, RIMS President Dr Charles P. Shoemaker, Jr. and President-Elect Dr Paul J.M. Healey have presented the package to constituent societies in Kent County, Washington County, Newport, Woonsocket, and Pawtucket. It also has been the subject of meetings with the Rhode Island Bar Association.

Recent trends suggest a worsening of the professional liability situation in Rhode Island. It has been estimated that malpractice claims currently are pending against one of every three physicians in the state. According to the Medical Malpractice Joint Underwriting Association (JUA), 1,748 physicians paid a total of \$6,945,774 in premiums for 1982, the last year for which figures are available. Thirteen hospitals paid a total of \$1,804,684 to the JUA during that year.

OPTOMETRIC BILL DRAWS FIRE

During a packed March 28 hearing before the House Corporations Committee, representatives from the Rhode Island Medical Society and RI Ophthalmological Society opposed a bill which would permit optometrists to use therapeutic drugs to treat ocular disease.

While optometrists in 37 states, including Rhode Island, may use drugs for diagnostic purposes, prescription of therapeutic drugs is permitted only in West Virginia and North Carolina.

Testifying on behalf of the Society, Dr Milton W. Hamolsky, Physician-in-Chief, Department of Medicine, Rhode Island Hospital, and RIMS Secretary, told the committee that many ocular symptoms may be manifestations of general systemic disease which optometrists are not qualified to recognize. Dr Thomas Hutchinson, Harvard Medical School, said that "therapeutic drugs carry far greater hazards than diagnostic drugs." Also speaking against the bill were Drs. David S. Greer, Dean,

Brown University Program in Medicine; Robert S.L. Kinder, Chief of Ophthalmology, Rhode Island Hospital; H. Denman Scott, Deputy Director, RI Department of Health; and Alfred Lemoine, a Kansas City ophthalmologist.

Noting that only physicians have the experience and qualifications to deal with the systemic effects of therapeutic drugs, the Society and the state's ophthalmologists have called the bill a "public health threat." The legislative strategy has been coordinated by RI Ophthalmological Society President Dr Y. Jacob Schinazi.

MASS BLUES FOUND GUILTY OF PRICE-FIXING

In a victory for the Massachusetts Medical Society (MMS), Chief Judge Andrew A. Caffrey of the US District Court in Boston recently ruled that Massachusetts Blue Shield had violated the Sherman Anti-Trust Act. At issue was a provision which required Massachusetts physicians to accept reimbursement from the Blues as "payment in full" for their professional services. By forbidding the practice of "balance billing," Judge Caffrey said in a 59-page ruling that the Blues were guilty of "illegal price-fixing." The lawsuit, filed by four individual physicians and MMS, has been pending since 1978.

While most Blue Shield plans in other states prohibit balance billing by participating physicians, Massachusetts Blue Shield was able to force its reimbursement levels on physicians because of a unique state law which requires them to become "participating providers" as a condition of receiving any reimbursement. Since more than 60 per cent of the Bay State's residents are insured by the Blues, Massachusetts physicians often felt compelled to sign participation contracts as a means of economic survival. More than 98 per cent of the state's doctors belong to Massachusetts Blue Shield. Patients of the remaining two per cent could not receive any reimbursement from the Blues.

Judge Caffrey ruled that physicians

will not be permitted to balance bill until all judicial appeals have been exhausted. Massachusetts Blue Shield has announced plans to appeal the decision to the US Supreme Court.

STATE CANCER MORTALITY RATE HIGHER THAN US AVERAGE

The overall cancer mortality rate in Rhode Island for the period 1978 to 1982 was 11 per cent higher than the average national rate for the country.

This finding, according to the February 1984 final report of the Rhode Island Cancer Information System, places the state at a mortality level comparable to other urban areas in the United States.

Other significant conclusions in the report include:

- The cancer incidence rate, ie, the rate of newly-diagnosed cases, was within one per cent of the estimated national rate.
- The incidence and mortality rates for cancers of the colon, rectum, and lung were higher than the national average.
- The incidence and mortality rates for cancer varied with socioeconomic status. Residents of poverty areas experienced rates which were nearly 25 per cent higher than those for residents of more affluent communities.
- Middle-aged and older men were more likely than women of the same age to acquire and die from cancer. For those aged 75 and older, the incidence and mortality rates for men were double those for women.

Operated by the Rhode Island Health Services Research, Inc. (SEARCH) from July 1980 through June 1983, the Cancer Information Service registered new cases

of cancer among Rhode Island residents for the period 1978-1982. These accumulated data will form the basis for a cancer tumor registry in nine Rhode Island hospitals organized under the aegis of the Hospital Association of Rhode Island.

The Society's Cancer Committee, chaired by Dr Francis J. Cummings, is coordinating physician participation in the development of a tumor registry.

ANNUAL MEETING TO BE HELD NEXT MONTH

Invitations are in the mail for the 173rd Annual Meeting of the Rhode Island Medical Society on Wednesday, May 23, at the Providence Marriott.

The day's activities will start at noon with a luncheon for the House of Delegates. AMA President-Elect Dr Joseph F. Boyle, a Los Angeles internist, will present the keynote address to the assembled delegates. After the annual session of the House of Delegates at 2:00 pm, Dr Robert G. Petersdorf, Dean and Vice-Chancellor, University of California at San Diego Medical School, will present the 1984 Chapin Oration. Dr Petersdorf, a noted infectious disease specialist and administrator, will discuss the impact of government on medical practice.

The Chapin Oration will be followed by the annual membership business meeting at 4:30 pm, which will feature the Presidential Address of Dr Charles P. Shoemaker, Jr., presentation of awards, and the election of officers and committees.

After a brief reception, the evening banquet will begin at 6:30 pm. Margaret Heckler, Secretary, US Department of Health and Human Services, has been invited to present a keynote address. Her plans were pending as this issue of the Journal went to press. Music will be provided by the Nightscene.

Please call the Society's offices at 401/331-3207 for additional reservation forms.

PRACTICE MANAGEMENT QUESTION OF THE MONTH:

HOW LONG SHOULD MEDICAL RECORDS BE RETAINED?

One of the most frequently received questions at the Society's offices concerns medical records. While physicians need to know how long patient records should be kept, patients of retired or deceased members frequently call to find out where their medical records are located.

How long should records be retained?

Only five states -- Massachusetts, New Jersey, New York, Florida, and Oregon -- specify the length of time that physicians must maintain medical records for their patients. While there is no statutory requirement in Rhode Island, physicians must keep comprehensive patient records as long as the threat of a malpractice suit exists. The statute of limitations in each state determines the length of time a physician may be liable. In Rhode Island, malpractice litigation may be initiated up to three years after the alleged incident, or, in the case of a minor, three years after the patient reaches majority.

A recent issue of Legal Aspects of Medical Practice, a publication of the American College of Legal Medicine, underscores the role of complete medical records in a successful malpractice defense: "A physician unable to produce patient medical records in court because they were destroyed or discarded, or who can produce only partial medical records, will be in an extremely weak defensive position. Incomplete or damaged medical records create a legal inference that a physician acted in a deliberate dereliction of duty."

How should physicians provide access to medical records in case of retirement?

Before closing their offices, physicians should notify their patients and provide the name of the physician who will be taking over the practice. This will give patients the choice of obtaining service from the new physician or asking that their records be transferred to another doctor. A closing date for securing medical records should be announced.

RIMS members also should notify the Society (401/331-3207) where their patient records will be kept. This information will be retained in the membership file and provided to inquiring patients. In cases where it is not available, the patient will be told to send a written request to the Society where it is forwarded to the member's last known mailing address.

The Society also receives questions from the former patients of deceased members. In cases where no information is available about the transfer of records, we suggest that the patient call the probate court to obtain the name of the estate's executor.

For additional information . . .

A summary statement on "Rhode Island Physicians and Medical Records" will be sent to all RIMS members later this year. A revised version of a statement originally developed in October 1982, it is being prepared in cooperation with the Rhode Island Board of Medical Review and will reflect current state law. It will cover such items as patient requests, transfer of records, and disposition of records upon the retirement or death of a physician.



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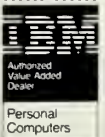
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An added complication... in the treatment of bacterial bronchitis*

Increasing incidence
of ampicillin resistance in
Haemophilus influenzae

Ampicillin Resistant
Haemophilus influenzae

H. influenzae

S. pneumoniae

Brief Summary Consult the package literature for prescribing information

Indications and Usage Cefaclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae* (*Diplococcus pneumoniae*), *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci).

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Cefaclor.

Contraindication: Cefaclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Cefaclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics including macrolides, semisynthetic penicillins, and cephalosporins; therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: **General Precautions**—If an allergic reaction to Cefaclor occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Cefaclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Cefaclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Cefaclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy—Pregnancy Category B—Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Cefaclor. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers—Small amounts of Cefaclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one

Some ampicillin-resistant strains of *Haemophilus influenzae*—a recognized complication of bacterial bronchitis*—are sensitive to treatment with Cefaclor.^{1,6}

In clinical trials, patients with bacterial bronchitis due to susceptible strains of *Streptococcus pneumoniae*, *H. influenzae*, *S. pyogenes* (group A beta-hemolytic streptococci), or multiple organisms achieved a satisfactory clinical response with Cefaclor.⁷

Cefaclor®

cefaclor

Pulvules®, 250 and 500 mg

hour. The effect on nursing infants is not known. Caution should be exercised when Cefaclor® (cefaclor, Lilly) is administered to a nursing woman.

Usage in Children—Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Cefaclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2-5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1-5 percent of patients and include morbilliform eruptions (1 in 100), pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthritis-like, frequently fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Cefaclor.

Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain—Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic—Slight elevations of SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic—Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

(061782R)

*Many authorities attribute acute infectious exacerbation of chronic bronchitis to either *S. pneumoniae* or *H. influenzae*.

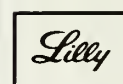
Note: Cefaclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285. Eli Lilly Industries, Inc., Carolina, Puerto Rico 00630.

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COVER:

During the period 1977-1982, 766 persons died in traffic accidents on Rhode Island highways and roads. For the second in a series of papers on the topic, see page 171.

Photograph courtesy of The Providence Journal.



MASTER HEALTH UPDATE

APRIL 1984

OCEAN STATE MASTER HEALTH PLAN, INC.

NEW PROVIDERS

The following providers have recently joined our health care network:

PHYSICIANS

Alexander Arvanitides, M.D.
Donald Bortle, D.O.
Richard J. Breed, M.D.
David Clark, M.D.
Joseph DiLorenzo, M.D.
David C. Ianacone, M.D.
Sheldon Lidofsky, M.D.
John D. Lowney, D.O.
Alan J. Weissburg, M.D.
Ernest Zuenä, M.D.

OPTOMETRISTS

John Clark, O.D.
Allen Greenberg, O.D.
Michael Saccucci, O.D.
Steven Croce, O.D.
Edward F. Richards, O.D.

PREVENTIVE HEALTH PROMOTION

OSMHP presents an Infant Car Seat to each new baby born after health care coverage with the Plan becomes effective. To date, there have been two healthy babies delivered at Kent County Memorial Hospital. Both infants were prepared to be buckled up for safety courtesy of OSMHP.

ENROLLMENT UPDATE

Spring is here and with it another growth surge. Enrollment is now at 3000 subscribers and growing daily.

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Physicians wishing to retain their patients who are considering switching health care coverage to OSMHP should contact our Provider Relations Department for details at 273-7050.

EDITORIALS

Take Care of Yourself

The Centers for Disease Control of the US Public Health Service recently reported the results of health risk surveys conducted in thirteen states and the District of Columbia. These surveys identify the major hazards to our health and point the way to a healthier life. The average results are

See also page 171.

reported below to provide a crude estimate of the key dangers of our contemporary lifestyles.

Sixty per cent of the respondents did not use seat belts. Failure to use seat belts is widespread among the entire population. Thirty-one per cent smoked cigarettes, and the habit was more common among women. Obesity was most prevalent among the middle-aged. Twenty per cent described themselves as "acute drinkers," or those who had consumed five or more drinks on at least one occasion during the previous month. Acute heavy drinking was highest for young men.

Thirteen per cent of the survey respondents had sedentary lifestyles, reflecting a low level of activity in exercise, work, and recreation. Sedentary living increased with age. Seven per cent were chronic heavy drinkers. A chronic heavy drinker was defined as a person whose average total alcoholic beverage intake exceeds 56 drinks a month. And five per cent reported the fatal combination of drinking and driving. Young males were most likely to drive while intoxicated. Finally, four per cent admitted to having uncontrolled high blood pressure, resulting from their failure to adhere to an antihypertensive regimen.

The eight behavior categories studied in these surveys are associated with eight of the ten leading causes of premature death. Together they may contribute to more than half the premature deaths in this country. The Centers for Disease Control conclude from these data that lifestyle changes offer a clear opportunity for many Americans to reduce the risks of premature death, disease, and disability. The way to healthy living lies in the use of seat belts, no smoking, appropriate exercise, and the prudent consumption of alcohol.

Data from Rhode Island also confirm the need for healthier lifestyles. In 1980, the Rhode Island Department of Health and SEARCH conducted the third in a series of health interview surveys of a random selection of Rhode Island households. The survey results indicate that an incredible eighty-two per cent of the state's residents do not use seat belts. Thirty-five per cent still smoke cigarettes, and of these, more than half smoke at least one pack a day. Among men in the 20-44 year-old age bracket, a shocking forty-four per cent smoke cigarettes. Fifty-nine per cent of Rhode Island women and forty-seven per cent of the male respondents do not exercise on a regular basis. And finally, seventy-one per cent of the state's population 16 years of age and older drink alcohol. Eight per cent of this group reported that they were drinking excessively.

A current Department of Health bumper sticker proclaims the best health advice for Rhode Islanders: "Take Care of Yourself."

William J. Waters, PhD
Assistant Director for Health Policy
Rhode Island Department of Health

The Association Copies of the Medical Society Library

[Helen DeJong, Librarian Emerita of the Rhode Island Medical Society, retired from the position in 1975 after 45 years of service to the Society. Her interest in the Library has not abated. She returns to Providence periodically to assist in the identifying, cataloguing, and preserving of archival materials and rare books. In 1962, Mrs. DeJong was named an honorary member of the Society.

In this historical note, Mrs. DeJong discusses some of

My instructions were to catalogue Doctor Hersey's 30,000 or so volumes as rapidly as possible before the funds ran out, not an infrequent occurrence during the 1930s. Obediently, I typed away with only an occasional peek into a tempting little, calf-bound book on kinepock, or fevers. I was aware that the book carried the signatures of the original owners and the fact of their significance to the Society's history, but there was no time for studying and noting provenance. During my years as librarian (1930-1975), I was able to spend a few hours here and there in pulling the "Association Copies" from the dusty stacks and placing them in proper storage. There was never time to perform a thorough search and study, so I promised myself that I would make this one of my volunteer "fun" projects during retirement.

During the summer of 1983, I started to check the 361 items belonging to the Society which are listed in *Early American Medical Imprints* by Robert B. Austin. All of these items are treasures and many of them were originally owned by such literate Rhode Island physicians as Isaac Senter (who died before the Society's establishment in 1812, but whose library was acquired by David King, Senior); Amos Throop; David King; Comfort Carpenter; Ezekiel Fowler; Levi Wheaton; Usher Parsons; and the businessman Moses Brown, whose interests included inoculation, tar water, and Perkins' tractors. In checking these books, I found Moses Brown's copy of *On the Kinepock* by John Coakley Lettsom, which con-

the valuable items to be found in the collection amassed by Doctor George Dallas Hersey (1847-1919). Doctor Hersey, a Providence physician and bibliophile, served as Librarian of the Rhode Island Medical Society from 1880 until 1913. His tenure was marked by a vigorous acquisitions policy, and at the time of his retirement, the Library collection had reached some 30,000 volumes. Ed.]

tains the inscription "To my friend Moses Brown from Benj. Waterhouse." As I pulled the small volume from the shelf, I felt the presence of the two gentlemen, and history became real. Another find, now in our pamphlet collection in the DeJong Room, was *Espozione de Tre Embriogenie* inscribed, "Procured by Dr Usher Parsons, when in Italy, about the year 1830 — Charles E. Parsons." The publication date is 1828.

Many of our "Association Copies" were in the case that housed Doctor Hersey's rare book collection and have since been moved to air-conditioned, humidity-controlled comfort: Doctor Throop's copy of William Saunders' *Observations on the Superior Efficacy of the Red Peruvian Bark*; George L. Collins' copies of the first three editions of *An Inquiry into the Causes and Effects of the Variole Vaccine* by Edward Jenner; and Usher Parsons' copy of Jacobus-René Tenon's *Memoires sur Les Hôpitaux de Paris*. Before his death, Doctor H. G. Partridge gave us his collection of medical texts, including such titles as Walter Channing's *A Treatise on Etherization in Childbirth* and a reprint of Oliver Wendell Holmes' *The Contagiousness of Puerperal Fever*.

It is likely that we shall find other important historical items as we weed the monograph collection. This is one reason why a careful book-by-book evaluation of the Library holdings is being made. It is a slow and dusty process, but an exciting one when you encounter Benjamin Waterhouse on the way.

Helen DeJong
Librarian Emerita
Rhode Island Medical Society

PRESIDENT'S PAGE



Non-Physician Health Care Providers: A More Systematic Approach is Needed

During the past ten years, the Rhode Island Medical Society has devoted considerable time and energy to blocking efforts by non-physician health providers to expand their professional roles and privileges. Rhode Island optometrists, as an example, are currently seeking authority to prescribe therapeutic drugs. In 37 states, including Rhode Island, they already are permitted to use diagnostic agents in their practices. Previous years have seen testimony from the Society against chiropractors, physician assistants, and other groups who have attempted to extend their practice privileges by legislative fiat. The primary focus of our concern has been to protect patients by requiring adequate training and experience for all providers of medical care. Yet each year, we find ourselves cast in the role of the establishment fighting the underdog and being accused of protecting our own financial interests.

The legislators and the governor have generally heeded advice from the medical society and other concerned organizations. As a result, the rules and regulations covering Rhode Island health care providers are similar to those in other states. One specialty, nurse practitioners, has not been defined by statute. While they examine, diagnose, and treat patients, their role and authority have not received legal status.

The General Assembly continues to examine bills concerning non-physician providers on a piecemeal basis. The time may well have come for a more systematic approach. We could avoid the annual "turf battle" among the various specialties by developing a master plan covering such issues as education, reimbursement, intraprofessional relationships, and so forth. Earlier this year, the Rhode Island Medical Society considered seeking



Charles P. Shoemaker, Jr., MD

the establishment of a legislative commission to study all health providers and to propose recommendations for licensing and regulating each specialty. Knowledgeable observers in the State House counseled against the proposal, however, and the bill was not submitted. It may be possible, working through the AMA, to develop some constructive guidelines on non-physician health care providers for the General Assembly. In the interim, the Society's Professional Health Care Providers Committee will continue its current series of meetings with non-physician groups to discuss shared problems and concerns. This constructive approach should help reverse our unsolicited role as policemen.

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Depression Following Cranial Radiation for Brain Tumor

Impaired Function Appeared to be Due to Tumor, Irradiation Therapy, or Both

Richard J. Goldberg, MD
Alan D. Steinfeld, MD
Robert M. Tull, PhD

The neuropsychiatric effects of therapeutic cranial irradiation are poorly understood and are currently under investigation.¹ One possible effect of such therapy is the development of symptoms of depression. In a seriously ill patient, such symptoms may be attributed prematurely to psychiatric illness, prompting inappropriate therapy. Psychometric tools are available which may help in differentiating emotional upset due to life crisis from those due to a medical illness, its treatment, or both.

The recent appearance in our clinic of a patient demonstrating emotional problems after cranial irradiation prompts this report.

Case Report

A 40-year-old white male presented at an emergency room following a grand mal seizure. Physical examination showed marked weakness, hyperreflexia, and a Babinski's sign on the right side. A computed tomographic (CT) scan showed

a left temporal lesion, and arteriogram showed an avascular mass of the temporal lobe. He was placed on Decadron®, Dilantin®, and phenobarbital and was discharged from the hospital for further observation. Repeat CT scans during the next two weeks showed decreasing amounts of edema and evidence of a mass in the left temporo-parietal area.

Past medical history revealed a brief course of psychotherapy for a situational depression ten years prior to the current illness.

Because of the deep location of the tumor as determined both by clinical and radiological evaluation, it was felt that biopsy or resection would leave the patient with a significant and permanent neurological deficit. Consequently, the patient was treated primarily with radiation. Forty-five hundred rads were delivered to the whole brain in 25 fractions. The primary tumor received an additional 1,950 rads in nine fractions.

After completion of the radiation therapy, the patient continued to have intermittent focal seizures for which carbamazepine (Tegretol®), Dilantin®, and Decadron® were required. Two months after completion of radiation therapy, a repeat CT scan and electroencephalogram (EEG) were carried out. The scan was now normal, showing no evidence of the previously noted tumor mass. The EEG revealed no focal or lateralizing abnormalities. Despite the absence of an objective neurological deficit, the patient apparently lacked motivation to return to work and was irritable at home. His wife and family noted a persistent lethargy. Repeated physical examinations and laboratory studies, including an endocrine evaluation, revealed no abnormalities. Consequently, he was referred for psychiatric evaluation of the depression approximately five months after the radiation treatment.

From the Departments of Psychiatry and Radiation Oncology, Rhode Island Hospital, and the Sections on Psychiatry and Radiation Medicine, Brown University Program in Medicine.

Richard J. Goldberg, MD, Assistant Professor, Section of Psychiatry and Human Behavior, Brown University Program in Medicine.

Alan D. Steinfeld, MD, Associate Professor of Radiology, New York University. At the time of this writing, he was Assistant Professor of Radiation Medicine, Brown University

Robert M. Tull, PhD, Instructor, Section of Psychiatry and Human Behavior, Brown University Program in Medicine.

Psychiatric Consultation

During the initial evaluation, the patient appeared somewhat resistant to discussing his problems. He acknowledged a number of symptoms consistent with depression: decreased interest in usual activities, diminished concentration, memory difficulties, inability to get any work done, decreased libido, and fatigue. He described his mood as subdued and intermittently discouraged, but not hopeless, and admitted no suicidal ideation. He stated that his sleep and appetite were normal. He felt that he had lost his appreciation for the coordination of form and color. He could not organize his work as a designer.

There was a prior history of a situational depression as noted. The family history was negative for psychiatric disorders. There was no history of substance abuse.

Initial diagnostic considerations included an emerging primary (autonomous) affective disorder, depression as a psychological reaction to a major life event (secondary affective disorder), or an organic mental disorder with affective features. Among possible causes of the organic mental disorder were recurrent tumor, a seizure disorder, anticonvulsant medication toxicity, or neuropsychological impairment.

The patient was referred for neuropsychological evaluation.

Neuropsychological Evaluation

The following tests were carried out: Wechsler Adult Intelligence Scale (WAIS), Wechsler Memory Scale, Halstead-Reitan Neuropsychological Test Battery, Benton Visual Retention Test, Minnesota Test for Differential Diagnosis of Aphasia, and Symbol Digit Modalities Test. A brief description of each of these tests appears below.

On the WAIS evaluation, the patient obtained a verbal, performance, and full scale of 91, 91, and 90 respectively. Based on the available information concerning his premorbid level of intelligence, the results suggested a dramatic decrease in intellectual ability. He experienced considerable difficulty in tasks designed to assess immediate memory, concentration, attention span, recall of immediate auditory information in proper sequence, abstract reasoning, and conceptual manipulation. Results from the Halstead-Reitan test suggested bilateral organic involvement. The remaining tests indicated deficits concerning flexibility of thought and judgment, and

Testing Batteries

Wechsler Adult Intelligence Scale (WAIS)

The WAIS is an individually administered composite test battery which ordinarily constitutes a substantial portion of the testing component of a neuropsychological examination.

It traditionally has served as the standard for the development of tests to measure intelligence levels, and is the most commonly used test of intellectual ability for research purposes. The battery consists of 11 subtests from which a composite score is tabulated. This score is considered an excellent predictor of academic achievement by evaluating verbal factors, perceptual organization, nonverbal organization, and spatial performance.

Wechsler Memory Scale (WMS)

The WMS is used for extensive exploration of memory and learning ability. It is generally regarded as an estimate of gross memory function.

Halstead-Reitan Neuropsychological Test Battery

This battery consists of numerous tests selected to help differentiate between patients with frontal lobe lesions and those with other lesions or normal subjects.

Benton Visual Retention Test

This test is a visual memory test that can be used to isolate the perceptual and memory components of a defective performance.

Minnesota Test for Differential Diagnosis of Aphasia

The Minnesota Test for Differential Diagnosis thoroughly evaluates the depth of communication disturbances in five areas: auditory, visual and reading, speech and language, visual-motor and writing disturbances, and numerical and mathematical processes.

Symbol Digit Modalities Test

The Symbol Digit Modalities Test can indicate cerebral dysfunction and reflect visual-perceptual, visual-scanning, or oculomotor defects, or general mental or motor slowing. Motor persistence, sustained attention, response speed, and visual motor coordination play significant roles in evaluating the performance of subjects on this test.

weakness concerning sequential planning skills, degree of flexibility in new situations, and organizing and integrating new information. There were no pronounced indications of speech or language disturbances.

Clinical Course

The uncovering of the neuropsychiatric deficits had important implications for understanding and managing the symptoms of this patient. Exhorting the patient to "snap out of it" or to "start pushing yourself" served only to frustrate him further. His apparent reluctance to adapt to his

new situation was not simply psychological resistance, but could be interpreted as a neurophysiological impairment involving the integration of new information and the planning of behavior. His failure to return to work was, in large part, due to his desire to avoid confronting disabilities which made him unable to perform tasks required at his job, rather than being the result of impaired motivation associated with depression. His behavior could be reconceptualized as a disability which could be approached in terms of a rehabilitative rather than a psychodynamic model. By assuming the therapeutic posture that the patient was partially "disabled" rather than "depressed," he was able to return to work, successfully accomplishing circumscribed tasks, rather than tackling more complex projects. The clinician, family, and patient, by reassessing their unrealistic expectations of a rapid resumption of his previous level of function, reduced unnecessary frustration.

Discussion

The diagnosis of depression should be made with care, following the guidelines set forth by the American Psychiatric Association. Casual observation of complaints such as lack of motivation or difficulty with concentration is of itself not adequate. The *Diagnostic and Statistical Manual of Mental Disorders* (3rd Edition) for a diagnosis of depression requires, in addition to a relatively persistent depressed mood, at least four of the following symptoms: change in appetite, sleep disturbance, fatigability, psychomotor agitation or retardation, loss of interest or pleasure in usual activities, feelings of self-reproach, impaired concentration, or suicidal ideation.² Specific interviews may be required before the diagnosis of depression can be made reliably.

The evaluation and treatment of depression in patients with an intracerebral tumor requires the cooperation of the psychiatrist, the internist, and the radiation oncologist. Depression in such patients may be the result of one or more aspects of the underlying disease, or may be entirely unrelated to it. It may be a direct manifestation of the tumor, of the treatment (surgery, radiation, or both), or of a reaction to a life crisis. Medical disorders, such as hypothyroidism, hypokalemia, presenile dementia, pernicious anemia, and drug toxicity can present symptoms mimicking a depressive episode and must be excluded.³ Metabolic encephalopathies constitute the commonest group of neurological complications in hospitalized cancer patients.^{4, 5} Repeated seizures may

produce symptoms either in the postictal phase or as a result of temporal lobe activity.⁶ Furthermore, many patients with brain tumors are placed on corticosteroids which can cause behavior abnormalities, either by masking or enhancing depression. Careful attention to, and use of rigid diagnostic criteria for affective disorders and screening for underlying medical problems will aid in the diagnosis.

While no statistics are available for the incidence of this sequence in patients with primary brain tumors, an extrapolation may be possible from other types of cancer. The incidence of depression in cancer patients has been reported as ranging from 23 to 58 per cent in various series.⁸⁻¹¹ Such estimates are confused by combining uncritically such variables as cancer sites, age groups, and various diagnostic criteria for depression. Moreover, the scales commonly used to quantify depression include such somatic symptoms as anorexia and fatigability, which are common to both depression and cancer.

Superimposed on this uncertain background of the psychiatric symptoms of brain tumors are the effects of radiation on the emotional state. Transitory deterioration of the neurological status (nausea, headaches, ataxia, drowsiness) has been reported in patients with intracranial tumors following radiation therapy. Residual intellectual disorders, including a reduction in some aspects of the intelligence quotient in children surviving such radiation, have also been observed.^{14, 15} It is not yet clear whether adult patients differ from children in terms of sequelae to cranial irradiation.

The incidence of neuropsychiatric changes resulting from radiation treatment of brain tumors has not been studied. In addition to documenting the frequency of such changes, the relative effect of factors, such as total dose, dose rate, type of radiation, and field size, needs to be clarified.

A depressive episode cannot be diagnosed reliably in the face of a concurrent organic mental disorder. Levine and his colleagues examined the records of 100 cancer patients referred for psychiatric consultation. While 56 were diagnosed by the referring physician as depressed, 26 were classified on psychiatric reassessment as actually suffering from an organic brain syndrome. Under such conditions, a neuropsychological testing battery such as the Halstead-Reitan test can differentiate patients with organic disease quite effectively. This patient demonstrates how symptoms of depression can be ascribed prematurely to a psychological reaction or other

psychiatric illness. After testing, his impaired attention, concentration, and ability to function at work were felt to be a consequence of neuropsychological damage secondary to the effects of

the brain tumor, to the irradiation treatment, or to both, and was successfully managed by a structured, rehabilitative treatment approach.

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Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Anti-hypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

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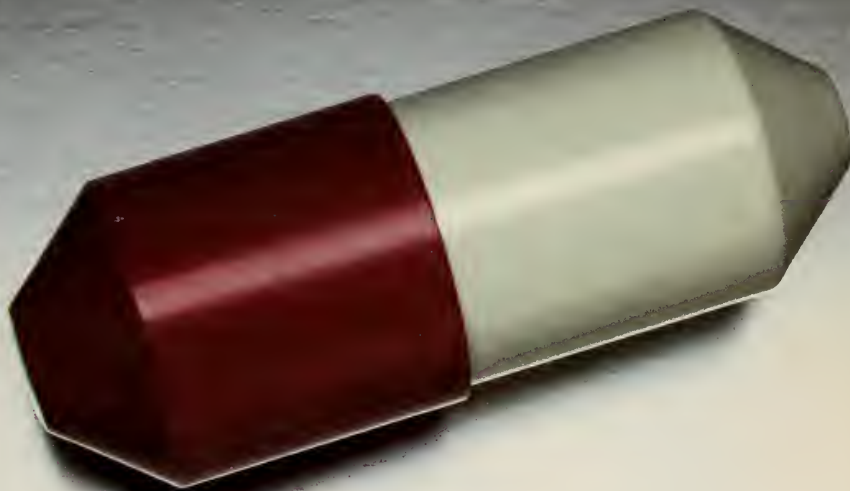
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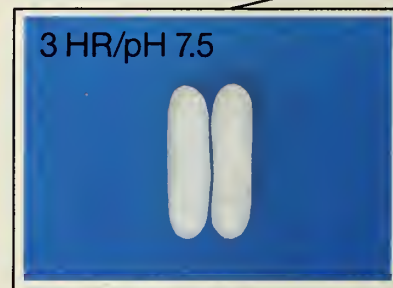
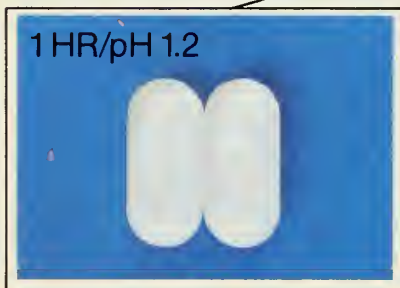


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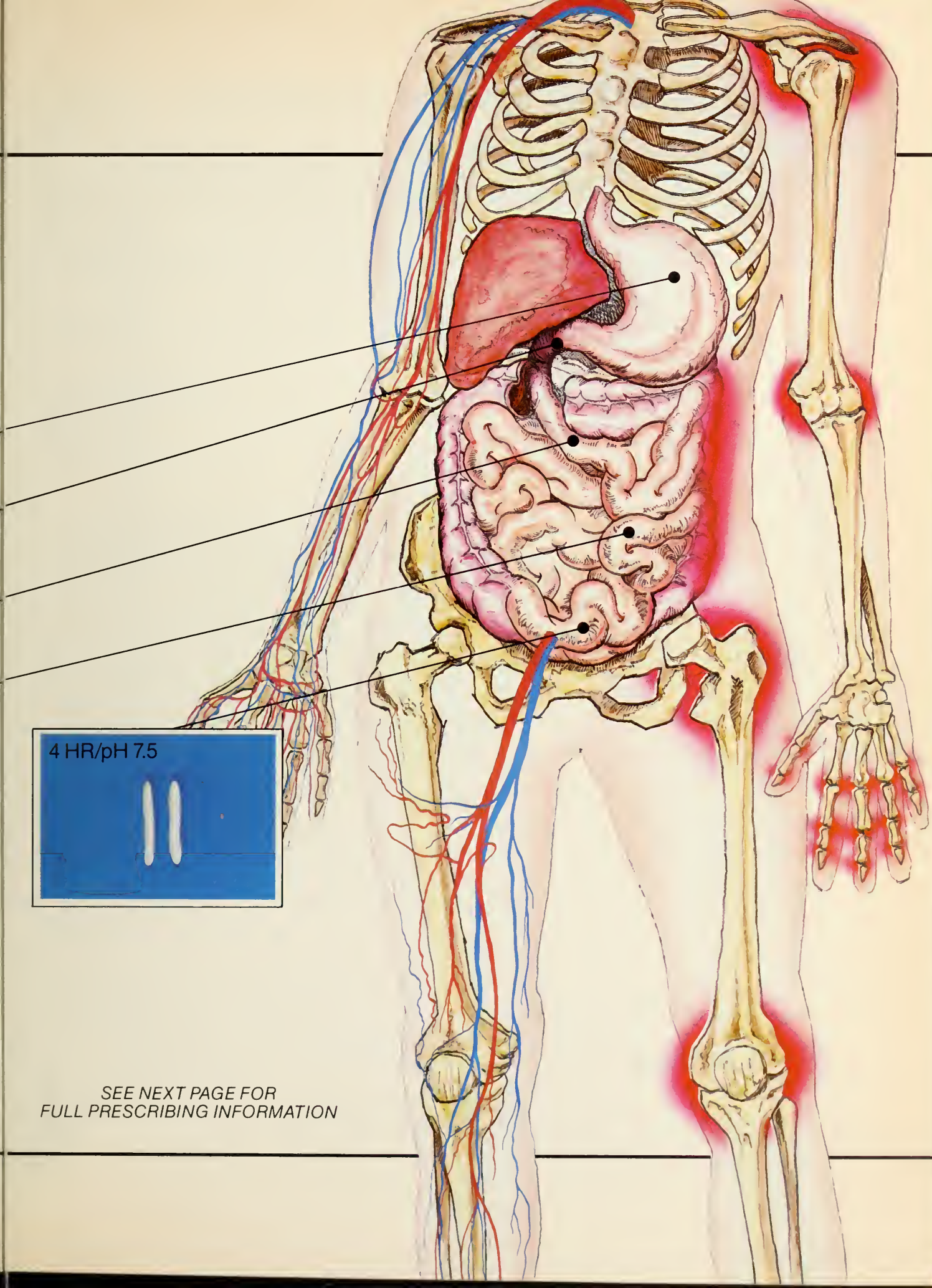
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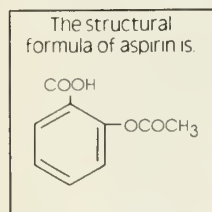


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ZORprin (ASPIRIN) Zero-Order Release

DESCRIPTION: Each capsule-shaped tablet of Zorprin contains 800 mg of aspirin, formulated in a special matrix to control the release of aspirin after ingestion. The controlled availability of aspirin provided by Zorprin approximates zero-order release; the *in vitro* release of aspirin from the tablet matrix is linear and independent of the concentration of the drug. **CLINICAL PHARMACOLOGY:** Aspirin, as contained in Zorprin, is a salicylate that has demonstrated anti-inflammatory and analgesic activity. Its mode of action as an anti-inflammatory and analgesic agent may be due to the inhibition of synthesis of prostaglandins, although its exact mode of action is not known. **Zorprin dissolution is pH-dependent.** *In vitro* studies have shown very little aspirin to be released in acidic solutions, whereas, Zorprin releases the majority of its aspirin (90%) in a zero-order mode at a neutral to alkaline pH. It is this pH dependence of Zorprin that reduces direct contact between aspirin and the gastric mucosa, resulting in a reduction of its gastrointestinal side-effect potential. **Bioavailability data for Zorprin have confirmed that plasma levels of salicylic acid and acetylsalicylic acid can be measured 24 hours after a single oral dose.** This substantiates a twice daily dose regimen. Multiple dose bioavailability studies showed similar steady-state salicylate levels for Zorprin as for conventional release aspirin using the same total daily dose. Long-term monitoring of salicylate levels showed no signs of accumulation once steady-state levels were reached (4-6 days). **Studies of *in vivo* prostaglandin levels (PGE2) have shown Zorprin plasma levels of salicylic acid and acetylsalicylic acid to reduce PGE2 levels 14 hours after a single oral 800 mg dose while an equivalent dose of aspirin produced a reduction of PGE2 levels only through six hours.** Zorprin's effect on prostaglandins other than PGE2 has not been determined. **Salicylates are excreted mainly by the kidney, and from studies in humans it appears that salicylate is excreted in the urine as free salicylic acid (10%); salicyluric acid (75%); salicylic phenolic (10%); acyl glucuronides (5%); and gentisic acid (<1%).** **INDICATIONS & USAGE:** Zorprin is indicated for the treatment of rheumatoid arthritis and osteoarthritis. The safety and efficacy of Zorprin have



not been established in those rheumatoid arthritis patients who are designated by the American Rheumatism Association as Functional Class IV (incapacitated, largely or wholly bedridden, or confined to wheelchair, little or no self-care). **In patients treated with Zorprin for rheumatoid arthritis and osteoarthritis, the anti-inflammatory action of Zorprin has been shown by reduction in pain, morning stiffness and disease activity as assessed by both the investigators and patients.** **In clinical studies in patients with rheumatoid arthritis and osteoarthritis, Zorprin has been shown to be comparable to conventional release aspirin in controlling the aforementioned signs and symptoms of disease activity and to be associated with a statistically significant reduction in the milder gastrointestinal side effects (see ADVERSE REACTIONS).** Zorprin may be well tolerated in some patients who have had gastrointestinal side effects with conventional release aspirin, but these patients when treated with Zorprin should be carefully followed for signs and symptoms of gastrointestinal bleeding and ulceration. **Since there have been no controlled trials to demonstrate whether or not there is any beneficial effect or harmful interaction with the use of Zorprin in conjunction with other nonsteroidal anti-inflammatory agents (NSAI), the combination cannot be recommended (see Drug Interactions).** **Because of its relatively long onset of action, Zorprin is not recommended for antipyresis or for short-term analgesia.** **CONTRAINDICATIONS:** Zorprin should not be used in patients known to be hypersensitive to salicylates or in individuals with the syndrome of nasal polyps, angioedema, bronchospastic reactivity to aspirin, renal or hepatic insufficiency, hypoprothrombinemia or other bleeding disorders. Zorprin is not recommended for children under 12 years of age, it is contraindicated in all children with fever accompanied by dehydration. **WARNINGS:** Zorprin should be used with caution when anticoagulants are prescribed concurrently, since aspirin may depress platelet aggregation and increase bleeding time. Large doses of salicylates may have hypoglycemic action and enhance the effect of the oral hypoglycemics, concomitant use therefore is not recommended. However, if such use is necessary, dosage of the hypoglycemic agent must be reduced. The hypoglycemic action of the salicylates may also necessitate adjustment of the insulin requirements of diabetics. **While salicylates in large doses have a uricosuric effect, smaller amounts may reduce water excretion and increase serum uric acid.** **USE IN PREGNANCY:** Aspirin can harm the fetus when administered to pregnant women. Aspirin interferes with maternal and infant hemostasis and may lengthen the duration of pregnancy and parturition. Aspirin has produced teratogenic effects and increases the incidence of stillbirths and neonatal deaths in animals. **If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.** **Aspirin should not be taken during the last 3 months of pregnancy.** **PRECAUTIONS:** Appropriate precautions should be taken in prescribing Zorprin for patients who are known to be sensitive to aspirin or salicylates. Particular care should be used when prescribing this medication for patients with erosive gastritis, peptic ulcer, mild diabetes or gout. As with all salicylate drugs, caution should be exercised in prescribing Zorprin for those patients with bleeding tendencies or those on anticoagulants. **In order to avoid exacerbation of disease or adrenal insufficiency, patients who have been on prolonged corticosteroid therapy should have their therapy tapered slowly rather than discontinued abruptly when Zorprin is made a part of the treatment program.** **Patients receiving large doses of aspirin and/or prolonged therapy may develop mild salicylate intoxication (salicylism) that may be reversed by dosage reduction.** **Salicylates can produce changes in thyroid function tests.** **Salicylates should be used with caution in patients with severe hepatic damage, preexisting hypoprothrombinemia, Vitamin K deficiency and in those undergoing surgery.** **Since aspirin release from Zorprin is pH dependent, it may change in those conditions where the gastric pH has been increased as a result of antacids, gastric secretion inhibitors or surgical procedures.** **Drug Interactions:** (See **WARNINGS**) Aspirin may interfere with some anticoagulant and antidiabetic drugs. Drugs which lower serum uric acid by increasing uric acid excretion (uricosurics) may be antagonized by the concomitant use of aspirin, particularly in doses less than 2.0 grams/day. Nonsteroidal anti-inflammatory drugs may be competitively displaced from their albumin binding sites by aspirin. This effect may negate the clinical efficacy of both drugs. Also, the gastrointestinal inflammatory potential of nonsteroidal anti-inflammatory drugs may be potentiated by aspirin. The combination of alcohol and aspirin may increase the risk of gastrointestinal bleeding. **Aspirin may enhance the activity of methotrexate and increase its toxicity.** **Sodium excretion produced by spironolactone may be decreased in the presence of salicylates.** Concomitant administration of other anti-inflammatory drugs may increase the risk of gastrointestinal ulceration. Urinary alkalizers decrease aspirin's effectiveness by increasing the rate of salicylate renal excretion. Phenobarbital decreases aspirin's effectiveness by enzyme induction. **Pregnancy Category D.** See **WARNINGS** Section. **Nursing Mothers:** Salicylates have been detected in the breast milk of nursing mothers. Because of the potential for serious adverse reactions from aspirin in nursing infants, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the benefit of the drug to the mother. **ADVERSE REACTIONS: Hematologic:** Aspirin interferes with hemostasis. Patients with a history of blood coagulation defects or receiving anticoagulant drugs or with severe anemia should avoid Zorprin. Aspirin used chronically may cause a persistent iron deficiency anemia. **Gastrointestinal:** Aspirin may potentiate peptic ulcer, and cause stomach distress or heartburn. Aspirin can cause an increase in occult bleeding and in some patients massive gastrointestinal bleeding. However, the greatest release of active drug from Zorprin is designed to occur in the small intestine over a period of time. This has resulted in fewer symptomatic gastrointestinal side effects. **Allergic:** Allergic and anaphylactic reactions have been noted when hypersensitive individuals have taken aspirin. Fatal anaphylactic shock, while not common, has been reported. **Respiratory:** Aspirin intolerance, manifested by exacerbations of bronchospasm and rhinitis, may occur in patients with a history of nasal polyps, asthma, or rhinitis. The mechanism of this intolerance is unknown but may be the result of aspirin-induced shunting of prostaglandin synthesis to the lipoxygenase pathway and the liberation of leukotrienes, e.g. slow-reacting substance of anaphylaxis. **Dermatologic:** Hives, rashes, and angioedema may occur, especially in patients suffering from chronic urticaria. **Central Nervous System:** Taken in overdoses, aspirin provides stimulation which may be manifested by tinnitus. Following initial stimulation, depression of the central nervous system may be noted. **Renal:** Aspirin rarely may aggravate chronic kidney disease. **Hepatic:** High doses of aspirin have been reported to produce reversible hepatic dysfunction. **OVERDOSAGE:** Overdosage, if it occurs, would produce the usual symptoms of salicylism: tinnitus, vertigo, headache, confusion, drowsiness, sweating, hyperventilation, vomiting or diarrhea. Plasma salicylate levels in adults may range from 50 to 80 mg/dl in the mildly intoxicated patient to 110 to 160* mg/dl in the severely intoxicated patient. An arterial blood pH of 7.1 may indicate serious poisoning. The clearance of salicylates in children is much slower than adults and should receive due consideration when aspirin overdoses occur in infants; salicylate half-lives of 30 hours have been reported in infants 4-8 months old. Treatment for mild intoxication should include emptying the stomach with an emetic, or gastric lavage with 5% sodium bicarbonate. Individuals suffering from severe intoxication should, in addition, have forced diuresis by intravenous infusions of sodium bicarbonate and dextrose or sodium lactate. In extreme cases, hemodialysis or peritoneal dialysis may be required. **(*A plasma salicylate level of 160 mg/dl in an adult is usually considered lethal.)** **DOSAGE & ADMINISTRATION:** *In order to achieve a zero-order release, the tablets of Zorprin should be swallowed intact.* *Breaking the tablets or disrupting the structure will alter the release profile of the drug.* *It is recommended that Zorprin be taken with sufficient quantities of fluids (8 oz. or more).* **Adult Dosage:** For mild to moderate pain associated with rheumatoid arthritis and osteoarthritis, the recommended initial dose of Zorprin is 1600 mg (2-800 mg tablets) twice a day. Because of Zorprin's prolonged release of aspirin into the bloodstream, Zorprin tablets may be taken as a b.i.d. dose. Further adjustment of the dosage should be determined by the physician, based upon the patient's response and needs. Since it will take 4-6 days to reach steady-state levels of salicylic acid with Zorprin, it is recommended dosages be given for at least one week before further adjustment. In general, patients with rheumatoid arthritis seem to require higher doses of Zorprin than do patients with osteoarthritis. **Zorprin is not recommended for children below the age of 12.** **HOW SUPPLIED: Zorprin Tablets 800 mg;** plain, white capsule-shaped tablets. **Bottles of 100 Tablets—NDC 0524-0057-01.** **Caution:** Federal law prohibits dispensing without prescription. **U.S. Patent No. 4,308,251** **Manufactured and Distributed by: BOOTS PHARMACEUTICALS, INC., Shreveport, Louisiana 71106 U.S.A.**

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Traffic Fatalities in Rhode Island: Part II

The Timing of Accidents and the Role of Marital Status, Alcohol, and Psychoactive Drugs

The Role of Alcohol in Traffic Fatalities Is Again Emphasized

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The epidemiologic characteristics of traffic fatalities in Rhode Island for the years 1977-1982 are summarized as a series of papers appearing in this *Journal*. A total of 766 traffic deaths constitutes the basis for these reports, including all deaths, "... which involved one or more motorized vehicles, and their loads, in motion on a roadway which is open to the public and customarily used for motor vehicle travel."¹

The first paper in this series describes epidemiologic observations concerning the traffic accident victims and their representation within the Rhode Island population at risk.² Approximately half of these 766 traffic fatalities were males below the age of 34 years. The males killed in traffic accidents were more commonly drivers, while the females killed were more likely to be passengers or pedestrians. The number of traffic fatalities in persons above the age of 75 years was relatively small in this series, representing only 1.4 per cent of deaths. As the denominator

population, ie, elderly at risk, was substantially smaller, however, the age-specific mortality rates of the elderly groups were actually in the same range as the 15-34 year old population. During the six-year period, motor vehicle driver deaths accounted for 41.6 per cent of all traffic fatalities, while motorcycle deaths were responsible for an additional 12.7 per cent; passenger deaths represented 23.0 per cent and pedestrian deaths an additional 22.6 per cent of the 766 recorded fatalities.

The present paper is designed to identify some of the measurable risk factors associated with these traffic fatalities and to provide a quantitative framework within which these identified risks are distributed in the population of Rhode Island. If, as an example, vehicular failure is believed to be the primary cause of traffic deaths, a random distribution of traffic fatalities within the population should emerge, after appropriate standardization for such variables as miles driven, ambient weather, and circumstances of visibility. If, on the other hand, such personal characteristics as age, marital status, and drinking habits predominate as influential factors, a statis-

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This and subsequent papers in this series represent undergraduate honors studies undertaken at Brown University, Providence, Rhode Island. At the present time, Kemi Nakabayashi is a medical student at Case Western Reserve University; Sarah C. Aronson is a medical student at Dartmouth Medical School; and

Michael Siegel continues his undergraduate studies at Brown University. William Q. Sturner, MD, is Chief Medical Examiner, State of Rhode Island, and Professor of Pathology, Brown University Program in Medicine. Stanley M. Aronson, MD, is University Professor of Medical Science, Brown University.

Table 1. — Traffic Fatalities in Rhode Island:
Age, Sex, and Month of Fatal Accident

	Male (Age)					Female (Age)				
	0-14	15-34	35-64	≥65	Total	0-14	15-34	35-64	≥65	Total
January:										
Number	2	23	12	8	45	3	3	4	7	17
Per Cent	5.1	6.6	11	13.3	8.1	13.6	2.8	8.5	19.4	8.1
February										
Number	2	23	3	4	32	1	12	4	2	19
Per Cent	5.1	6.6	2.8	6.7	5.8	4.5	11.3	8.5	5.6	9
March										
Number	4	17	9	7	37	1	6	1	1	9
Per Cent	10.6	4.9	8.3	11.7	6.7	4.5	5.7	2.1	2.8	4.3
April										
Number	5	22	13	6	46	5	7	3	4	19
Per Cent	12.8	6.3	11.9	10	8.3	22.7	6.6	6.4	11.1	9
May										
Number	11	35	8	3	57	0	3	5	1	9
Per Cent	28.2	10.1	7.3	5	10.3	0	2.8	10.6	2.8	4.3
June										
Number	3	51	9	1	64	1	8	6	0	15
Per Cent	7.7	14.7	8.6	1.7	11.5	4.5	7.5	12.8	0	7.1
July										
Number	2	33	7	8	50	2	8	3	1	14
Per Cent	5.1	9.5	6.4	13.3	9	9.1	7.5	6.4	2.8	6.6
August										
Number	1	34	12	3	50	3	12	2	2	19
Per Cent	2.6	9.8	11	5	9	13.6	11.3	4.3	5.6	9
September										
Number	4	25	7	6	42	2	17	2	4	25
Per Cent	10.6	7.2	6.4	10	7.6	9.1	16	4.3	11.1	11.8
October										
Number	1	30	9	5	45	3	11	9	6	29
Per Cent	2.6	8.6	8.3	8.3	8.1	13.6	10.4	19.1	16.7	13.7
November										
Number	3	27	11	3	44	1	12	4	1	18
Per Cent	7.7	7.8	10	5	7.9	4.5	11.3	8.5	2.8	8.5
December										
Number	1	27	9	6	43	0	7	4	7	18
Per Cent	2.6	7.8	8.3	10	7.7	0	6.6	8.5	19.4	8.5
Total Number	39	347	109	60	555	22	106	47	36	211
Total Per Cent	100.7*	99.9	100.3	100	100	99.7	99.8	100	100.1	99.9

* Because of rounding, some total per cent figures may vary slightly.

tical correlation between these identified risk categories and the rate of traffic fatalities should be evident.

A review of records provided by the Office of the Medical Examiner revealed information concerning the following variables, each of which was examined further for nonrandom distribution: time of fatal accident (month, day, hour), marital status of victim, blood alcohol concentration and detection of illicit drugs in the victim, and type of vehicle.

Time of Accident

Table 1 summarizes the month of occurrence of the 766 fatal accidents and further analyzes the data according to the age and sex of the victims. Information pertaining to all 766 victims is included, regardless of their status as drivers, passengers, or pedestrians. Among the male victims below the age of 14 years, 67 per cent of the deaths occurred during the spring and summer months (observed to expected ratio (O/E = 1.33)).* With increasing age, this spring and summer clustering diminishes to a frequency of 46.7 per cent in male victims aged 65 years or older (O/E = 0.93). A similar declining trend in spring/summer fatalities characterizes the female vic-

tims. Among women, the percentage decreases from 54.4 per cent in those below the age of 14 years (O/E = 1.09) to 25.1 per cent in those older than 65 years of age (O/E = 0.5).

The fraction of traffic fatalities occurring in the winter, however, increases with age. In males below the age of 14 years, winter fatalities account for 12.8 per cent of the recorded traffic deaths. This proportion rises to 30 per cent in males aged 65 years or older. A similar age-related increase in the fraction of deaths taking place during the winter is seen with the female victim population where the level rises from 18.1 per cent below age 14 years to 44.4 per cent in females who are 65 years or older. Among all traffic victims 65 years of age or older, 28 of the 96 fatalities (29.2 per cent) occurred during December and January, constituting a relative risk for these months of 1.75.

The traffic fatalities in Rhode Island and their relationship to the day of the week are summarized in Table 2. Traffic fatalities are clustered on Fridays, Saturdays, and Sundays, while the fewest number of deaths are recorded on Tuesdays. This distribution corresponds to the pattern of traffic deaths during the past ten years for the nation as a whole.^{1, 3} A weekend concentration of traffic fatalities is most dramatically noted in the 15-34 year age group. This clustering of traffic fatalities, however, does not appear in victims below the age of 14 years and is negligible in victims above the age of 65 years. Table 2 also provides the ratios of *observed* and *expected*

* The abbreviation O/E, used in the text, represents a ratio of an *observed* number divided by an *expected* number. The *expected* number was determined by assuming a random distribution of cases. Thus, if O/E = 1.0, this would signify that the *observed* number conforms to a random distribution; if O/E is more than 1.0, it suggests a clustering of cases, while a value of less than 1.0 indicates the reverse.

Table 2. — Traffic Fatalities in Rhode Island:
Day of Fatality and Age of Victim

	Age				Total	Percentage RI	Distribution US†
	0-14	15-34	35-64	≥65			
Sunday	11	81	29	12	133	17.4	16.8
Monday	9	58	18	18	103	13.4	10.9
Tuesday	9	38	14	11	72	9.4	10.7
Wednesday	9	38	17	15	79	10.3	11.3
Thursday	7	47	18	13	85	11.1	12.3
Friday	11	62	31	8	112	14.6	16.7
Saturday	5	129	29	19	182	23.8	21.3
Total	61	453	156	96	766	100.0	100.0
Weekend: observed	16	210	58	31	315		
Weekend: expected*	17.4	129.4	44.6	27.4	218.9		
Ratio (O/E)	0.92	1.62	1.30	1.13	1.44		

*Expected weekend fatalities assuming a random distribution of traffic fatalities

†Source: Fatal Accident Reporting System

Table 3. — Traffic Fatalities in Rhode Island:
Hour of Fatality, Age, and Sex

	Hour of Day*	0-14	Age 15-34	35-64	≥65	Total	Percentage Per Time Interval
MALE	1- 3	1	121	19	3	144	25.9
	4- 6	0	12	2	1	15	2.7
	7- 9	1	9	5	5	20	3.6
	10-12	2	8	7	13	30	5.4
	13-15	9	22	16	11	58	10.5
	16-18	16	32	12	8	68	12.3
	19-21	8	50	23	13	94	16.9
	22-24	2	93	25	6	126	22.7
	Total	39	347	109	60	555	100.0
FEMALE	1- 3	1	43	5	0	49	23.2
	4- 6	1	2	2	0	5	2.4
	7- 9	1	2	3	4	10	4.7
	10-12	0	5	2	9	16	7.6
	13-15	1	7	5	8	21	10.0
	16-18	10	10	9	9	38	18.0
	19-21	5	13	11	5	34	16.1
	22-24	3	24	10	1	38	18.0
	Total	22	106	47	36	211	100.0

*A 24-hour clock is used

weekend fatalities tabulated according to the age of the victim.

Traffic fatalities, analyzed by hour of accident, age, and sex of victim are detailed in Table 3. One of every four traffic fatalities in Rhode Island occurs between midnight and 3 am. Most of the male fatalities (66.5 per cent) occur during the nine-hour period from 6 pm to 3 am, and 57.3 per cent of the female traffic accident victims are similarly clustered within this interval. A late night concentration of fatal accidents, however, is not evident in victims younger than 14 years of age. Indeed, 49 of the 61 fatalities (80.3 per cent) in this age group happened during the nine-hour daylight interval from noon to 9 pm. In contrast, 437 of the 609 victims between the ages of 15 and 64 years (71.8 per cent) were involved in fatal accidents between the hours of 6 pm and 3 am. Contrary to the time pattern of fatalities in persons aged 15 to 64 years, the elderly appear to be somewhat more vulnerable to traffic fatalities during the midday and afternoon hours. Fifty-eight of the 96 fatalities in individuals older than 65 years of age (60.4 per cent) took place between the hours of 9 am and 6 pm.

Marital Status

The marital status of the traffic victims in this series, analyzed by sex, is summarized in Table 4.

These data are compared to similar information provided by the US Census Bureau concerning the marital status in 1980 of the Rhode Island population as a whole.⁴ Male traffic victims, regardless of age, constitute a lower proportion who were married. They represent a correspondingly higher percentage who were either single or "other" (divorced, separated, or widowed). When compared with the total Rhode Island population, the group of male traffic victims contains substantially more individuals who are divorced, separated, or widowed. This lower frequency of marriage also is apparent among female traffic victims between the ages of 25 and 64 years.

Blood Alcohol and Psychoactive Drug Concentration

Information concerning postmortem blood alcohol concentrations was available for approximately 90 per cent of the 766 traffic deaths which occurred during the six-year period. Table 5 summarizes the mean blood alcohol concentrations according to the status of the victim, ie, driver, passenger, or pedestrian. In the 691 victims where the blood alcohol concentration was determined, a measurable level of alcohol was detected in 369 victims (53.4 per cent). For the purpose of this study, a blood alcohol concentra-

tion of 0.06 gm per cent was adopted as the threshold level for determining the clinical effects of alcohol. In most jurisdictions, including Rhode Island, the level of "legal" intoxication is established as 0.1 gm per cent. Some 59.7 per cent of the drivers killed in traffic accidents revealed concentrations which met or exceeded the threshold point of 0.06 gm per cent. Among those fatally injured drivers where blood alcohol was measured, 15.3 per cent showed blood concentrations in excess of 0.26 gm per cent.

Significant blood alcohol concentrations were not confined to the fatally injured motor vehicle drivers. Some 46.3 per cent of the fatally injured passengers and 24.3 per cent of the fatally stricken pedestrians also had concentrations at or above 0.06 gm per cent. Indeed, if children are deleted from the denominator, the degree of blood alcohol concentration among pedestrian victims approximates that of the fatally injured drivers.

In Table 6, the blood alcohol concentrations are related to the sex of the victim and the hour of the accident. About 80 per cent of all victims killed between the hours of midnight and 3 am demonstrate alcohol levels at or above 0.06 gm per cent. In contrast, during the period from sunrise to noon, only a negligible number of accidents are associated with elevated blood alcohol.

Of the 70 fatalities recorded between 6 am and noon, only 6 (8.6 per cent) were determined to have blood alcohol concentrations at or above the 0.06 gm per cent threshold.

Table 7 relates three variables, marital status, sex, and blood alcohol concentration, as risk factors which may affect traffic fatalities. Among males, the highest alcohol concentrations were present in divorced, single, or separated victims. A similar finding is evident among female victims. The lowest incidence of blood alcohol concentrations at or above 0.06 gm per cent occurs in those who are either married or widowed. The higher frequencies of significant blood alcohol concentrations in single, widowed, or separated victims becomes even more dramatic when victims younger than 15 years of age and older than 65 years are excluded from the computations.

Table 8 analyzes the 319 fatally injured drivers in terms of age and blood alcohol concentration. Among those driver fatalities with determined blood alcohol concentrations, the percentage showing the absence of blood alcohol rises with increasing age in both males and females. In only 10 per cent of fatally injured male drivers and 28.6 per cent of fatally injured female drivers above the age of 65 years has alcohol been detected in the blood stream.

Semi-quantitative analyses of various psycho-

Table 4. — Traffic Fatalities in Rhode Island:
Marital Status (Per Cent) and Sex*

	15-24	25-34	35-44	Age 45-54	55-64	65-74	≥75
Males: Traffic Fatalities							
Single	90.7	36.6	15.4	5.0	4.2	14.8	7.1
Married	7.0	49.5	66.7	77.5	75.0	55.6	53.6
Other	2.3	13.9	17.9	17.5	20.8	29.6	39.3
Males: Rhode Island							
Single	88.2	27.4	9.1	7.2	7.6	7.2	6.5
Married	10.8	64.7	81.2	83.0	82.9	78.0	64.6
Other	1.0	7.9	9.7	9.8	9.5	14.8	28.9
Females: Traffic Fatalities							
Single	85.5	31.3	13.3	0	18.2	0	26.1
Married	12.9	50.0	60.0	78.6	36.4	60.0	17.4
Other	1.6	18.7	26.7	21.4	45.4	40.0	56.5
Females: Rhode Island							
Single	79.1	17.7	7.4	7.3	7.7	10.8	13.2
Married	18.4	68.9	76.0	75.9	67.8	46.5	18.6
Other	2.5	13.4	16.6	16.8	24.5	42.7	68.2

*The age-stratified marital status of the total male and female population of Rhode Island for the year 1980, expressed as percentages, was computed from US Bureau of the Census tapes. The age-stratified marital status of the traffic fatalities was based only on those cases where the status was known (701 of 766 fatalities, or 91.5 per cent)

active pharmacologic agents were performed on the postmortem sera of 673 traffic fatality victims. Positive reactions for a marijuana metabolite (Δ -9 tetrahydrocannabinol, Δ 9THC) were obtained in 4.5 per cent of male victims and 2.2 per cent of female victims. The presence of barbiturates was determined in 0.8 per cent of males and 2.2 per cent of females. Approximately 6.8 per cent of all victims revealed some psychoactive substance in detectable concentrations.

An attempt was made to determine whether any of these agents were used in conjunction with alcohol. About 47.3 per cent of all victims had blood alcohol levels at or above 0.06 gm per cent. Of those with detectable barbiturate concentrations, about 37.5 per cent had alcohol levels at or above 0.06 gm per cent. All of those with detectable Δ 9THC concentrations had concurrent alcohol levels at the threshold level.

Type and Age of Vehicle

Among driver fatalities, excluding motorcycle deaths, 56.1 per cent of the victims were driving a conventional sedan, 36.8 per cent a compact automobile, and 7.1 per cent a truck. Among pedestrian deaths, the type of vehicle responsible for the fatal accident included sedans (59.1 per cent), compact automobiles (18.2 per cent), trucks (15.9 per cent), and motorcycles (6.8 per cent).

In most instances, the age of the vehicle was recorded. The vehicle was older than six years in 47.2 per cent of fatal accidents, between two and six years old in 24.2 per cent, and less than two

years old in 28.6 per cent.

Discussion

Traffic injuries and traffic fatalities are not distributed randomly. Rather, they tend to cluster around certain times of the day, week, or year; certain terrains or settings; and certain types of persons. The findings of this study corroborate the conclusions of others that the times of greatest risk for children are the months of March, April, and May. Most fatal traffic accidents involving children below the age of 14 years occur during the spring and summer months when the daylight hours are extended and children are more likely to play in or near streets. While the number of miles driven per person diminishes in the winter months, the likelihood of driver fatality increases, especially among older drivers.

The day of the week represents another skewed pattern. Most fatal accidents on Rhode Island roads take place consistently between Friday evening and Sunday. This weekend clustering, however, is apparent only with the driver fatalities, especially those between the ages of 18 and 35 years. Most of the fatal accidents in persons below the age of 14 years and above the age of 65 involve pedestrians or passengers rather than drivers. Pedestrian and passenger deaths are more randomly distributed throughout the week.

While the peak hours for driver fatalities are largely between midnight and 3 am, pedestrian fatalities, in contrast, are more common in the daylight hours.

Table 5. — Traffic Fatalities in Rhode Island:
Status of Victim and Blood Alcohol Concentration

Status of Victim	Number	Not Measured	0	Blood Alcohol Concentration (gm per cent)			Number and Per Cent ≥0.06*
				0-0.05	0.06-0.25	≥0.26	
Motor Vehicle:							
Driver	319	31	102	14	128	44	172/288 = 59.7%
Passenger	164	15	62	18	57	12	69/149 = 46.3%
Motorcycle:							
Driver	97	6	44	5	34	8	42/91 = 46.2%
Passenger	12	1	3	1	7	0	7/11 = 63.6%
Pedestrian	173	21	111	4	30	7	37/152 = 24.3%
Unknown	1	1	0	0	0	0	0/0 = 0.0%
Total	766	75	322	42	256	71	327/691 = 47.3%
			46.6%**	6.1%	37.0%	10.3%	

*Percentage determined by total number of fatalities with blood alcohol concentrations greater than 0.06 gm per cent divided by number of deaths in which blood alcohol concentrations have been determined

†Percent of those fatalities in which blood alcohol concentrations were determined (691 of the 766 fatal cases studied)

Table 6. — Traffic Fatalities in Rhode Island:
Hour of Fatality and Blood Alcohol Concentration

	Hour of Day*	Not Measured	Blood Alcohol Concentration (gm per cent)				Number and Per Cent $\geq 0.06^\dagger$
			0	0-0.05	0.06-0.25	>0.26	
MALE	1- 3	11	17	9	89	18	107/133 = 80.5%
	4- 6	1	6	0	6	2	8/14 = 57.1
	7- 9	1	17	1	1	0	1/19 = 5.3
	10-12	3	26	0	1	0	1/27 = 3.7
	13-15	11	32	3	9	3	12/47 = 25.5
	16-18	6	44	1	13	4	17/62 = 27.4
	19-21	11	45	2	28	8	36/83 = 43.4
	22-24	7	34	11	56	18	74/119 = 62.2
Total		51	221	27	203	5	256/504 = 50.8%
FEMALE	1- 3	2	5	5	27	10	37/47 = 78.7%
	4- 6	0	2	2	1	0	1/5 = 20.0
	7- 9	0	9	0	0	1	1/10 = 10.0
	10-12	2	11	0	2	1	3/14 = 21.4
	13-15	0	19	1	1	0	1/21 = 4.8
	16-18	10	20	2	6	0	6/28 = 21.4
	19-21	6	17	3	5	3	8/28 = 28.6
	22-24	4	18	2	11	3	14/34 = 41.2
Total		24	101	15	53	18	71/187 = 38.0%

*A 24-hour clock is used

† numerator = number of fatalities with blood alcohol concentrations >0.06 gm per cent

denominator = number of fatalities in which blood alcohol concentrations have been determined

Table 7. — Traffic Fatalities in Rhode Island:
Marital Status and Blood Alcohol Concentration

		Not Measured	0	0-0.05	Blood Alcohol Concentration (gm per cent)			
					0.06-0.25	0.16-0.25	>0.26	Per Cent >0.06*
MALE	Single	22	76	17	66	50	20	59.4%
	Married	15	82	5	19	31	19	44.2
	Widowed	4	12	1	4	2	0	31.6
	Divorced	4	9	2	3	5	6	56.0
	Separated	0	1	0	3	2	1	85.7
	Status Unknown	3	12	1	5	13	7	65.8
		48	192	26	100	103	53	54.0%
FEMALE	Single	9	28	7	14	9	9	47.8%
	Married	7	29	3	6	10	3	37.3
	Widowed	3	16	2	3	0	1	18.2
	Divorced	0	1	2	2	3	1	66.7
	Separated	0	2	0	0	0	0	0
	Status Unknown	0	11	1	1	5	4	45.5
		19	87	15	26	27	18	41.0%

*numerator = number of fatalities with blood alcohol concentrations >0.06 gm per cent

denominator = number of fatalities in which blood alcohol concentrations have been determined

Table 8. — Traffic Fatalities in Rhode Island:
Driver Fatalities, Age, and Blood Alcohol Concentration

	Age of Driver-Victim						Total (15 +)
	15-24	25-34	35-44	45-54	55-64	≥65	
Number of Male Driver Fatalities:	100	54	24	27	16	25	246
Number of BAC Not Measured	11	4	1	3	1	5	25
Number of Positive BAC	68	39	18	14	6	2	147
Number of Negative BAC	21	11	5	10	9	18	74
Percentage of Negative BAC*	23.6	22	21.7	41.7	60	90	33.5
Number of Female Driver Fatalities:	22	20	11	6	6	8	73
Number of BAC Not Measured	1	1	1	1	1	1	6
Number of Positive BAC	17	14	4	1	1	2	39
Number of Negative BAC	4	5	6	4	4	5	28
Percentage of Negative BAC*	19	26.3	60	80	80	71.4	41.8

*Percentage = Number of negative BAC Number measured × 100

When marital status was studied as an independent variable, the highest age-specific mortality rates were encountered in those of either sex who were divorced, separated, or single.

The Office of the Medical Examiner routinely examines the blood of traffic accident victims for alcohol and a variety of psychoactive drugs. A measurable concentration of alcohol was found in most driver fatalities, especially those killed in late night accidents. A substantial proportion of stricken passengers and pedestrians also have elevated blood alcohol levels. As the age of the victim increases, alcohol appears to play a less significant role, an observation previously made by others.⁵

Psychoactive drugs were detected in close to 7 per cent of the traffic deaths. When marijuana

was identified, it was invariably associated with alcohol and predominantly in fatal accidents occurring between midnight and 3 am. The frequency of marijuana detection was substantially higher in fatally-injured drivers than in fatally-injured passengers or pedestrians.

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RADIOGRAPHIC CASE OF THE MONTH

Sanford L. Schatz, MD
Howard R. Cohen, MD
Allan M. Deutsch, MD
Michael J. Ryvicker, MD

Department of Radiology
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History

This young patient complained of pressure in her ear and had a conductive hearing loss.



Fig 1. Coronal tomographic view through the petrous bone and middle ear.

For discussion turn to next page.

Radiographic Findings

In the computed tomographic (CT) scan, the coronal slices show a small sharply defined mass in the hypotympanum abutting on the lower tympanic membrane (Fig 2-arrow). There is no bone erosion. An air lucency extends beneath the mass, placing its origin in the tympanic cavity. This was confirmed by arteriography and venography.

Diagnosis

Glomus tympanicum tumor.

Discussion

This glomus tympanicum tumor belongs to a group of lesions also known as chemodectomas or non-chromaffin paragangliomas. They are named after their site of origin and arise from chemoreceptor cells of neural crest origin in the jugular fossa, middle ear, carotid body, ganglion nodosum, aortic arch, innominate artery, pulmonary artery, mediastinum, retroperitoneal area, abdominal aorta, and on lung surfaces. Although usually benign, they may be multicentric and may even metastasize through the lymphatic system or blood stream.

In the ear, these tumors arise within the tympanic plexus of the ninth nerve and are known as glomus tympanicum tumors or from the adventitia of the jugular bulb, in which case they are known as glomus jugulare tumors. As the mass grows, however, it may extend from the original site to an adjacent area, making the exact site of origin difficult to determine. They are commonly referred to as glomus jugulotympanicum tumors. There is a slight female predominance and familial occurrence.

In the ear, these tumors may destroy and erode the inferior aspects of the petrous pyramid; they may extend posteriorly to erode the jugular tubercle and extend into the hypoglossal canal. Extension into the foramen magnum, intracranial fossa, and the region of the cerebellar pontine angle have been reported. The tumor may present as an expansile pulsating mass in the middle ear to be differentiated on otological examination from a serous otitis.

Selective internal and external carotid angiography and venography are suggested to demonstrate the highly vascular nature of the mass



Fig 2. Coronal view through the middle ear cavity showing the soft tissue mass in the hypotympanum.

and vascular supply, and compression on the venous structures. These studies also confirm the nature of the tumor and exclude the possibility that the pulsating structure is the petrous portion of the internal carotid artery or the jugular bulb, both of which may enter the middle ear aberrantly. These studies also rule out an aneurysm of the petrous carotid artery extending into the middle ear cavity. A computed tomographic scan is considered to be the examination of choice for showing the anatomical configuration of the mass, its displacement of adjacent structures, and the areas of bone destruction.

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Alzheimer's Disease Presenting as Slowly Progressive Aphasia

This May Be the First Reported Case of This Sequence

Srecko Pogacar, MD
Roger S. Williams, MD

Progressive aphasia in mid to late life suggests a diagnosis of cerebral neoplasm. Subacute aphasia may also occur as a sequel of cerebral trauma and occult vascular disease in the elderly,¹ or as the first symptom of cerebral degenerative disorders, including Pick's disease²⁻³ and others which are not yet well classified on neuropathological examination.⁴ The case reported here is that of a man in his 50s who developed a fluent subacute aphasia that was the initial symptom of a slowly evolving cerebral degenerative disorder confirmed to be Alzheimer's disease on neuropathological examination. Although language disorders are frequently encountered during the course of Alzheimer's disease, to our knowledge this is the first case reported in which aphasia was the initial and most prominent clinical symptom.

Case Report

A right-handed insurance salesman developed a progressive language impairment at the age of 56 years. Proximate to the onset of neurological symptoms, he had fallen down a flight of stairs with apparently minor injury to his head and right shoulder. He had always been in good health with no past history of hypertension, car-

diovascular disease, or punctuated episodes of neurological deficit suggestive of cerebrovascular disease. The initial symptoms were subtle, consisting primarily of word-finding deficits. Between six and twelve months after onset, however, his skills in propositional speech and writing deteriorated to the extent that he had to quit work. His mathematical skills remained intact, and he managed his financial affairs effectively for the first ten to twelve months. Toward the end of the first year, he developed progressive difficulty in dressing, especially in orienting pullover shirts and in tying shoelaces. However, he continued to pursue effectively his favorite hobbies of woodworking and gardening and continued to drive without apparent difficulty. Neurologic examination at another hospital was normal except for the previously mentioned language deficits. The brain wave (EEG) and radionuclide cisternogram were normal, and computed tomographic (CT) brain scan was mildly abnormal because of atrophy of the left temporal lobe and enlargement of the left lateral ventricle (Fig 1).

When first seen by one of us (RSW) approximately 16 months after the onset of his illness, he exhibited a fluent aphasia with seemingly normal affect and deportment. There were frequent paraphasic errors, circumlocutions, and pauses with word-finding difficulty, especially for proper names. Paraphasic and grammatical errors were also made on repetitive tests. While he committed fewer errors when reading aloud, his reading comprehension was poor. He could sign his name and write his address legibly, but could not write a grammatical sentence. Calculations were done poorly, and there was left-right confusion. He followed two and three step commands with minimal difficulty and could mimic the use of scissors, toothbrush, comb, and razor to verbal cues. He was unable to button his clothing suc-

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cessfully. When presented with an outline map of the United States, he recognized it as such and could point to the location of major cities presented verbally. Although he copied complex geometric figures poorly, he was able to draw a diagram of the floor plan of his house and of his garden which, according to his wife, was quite

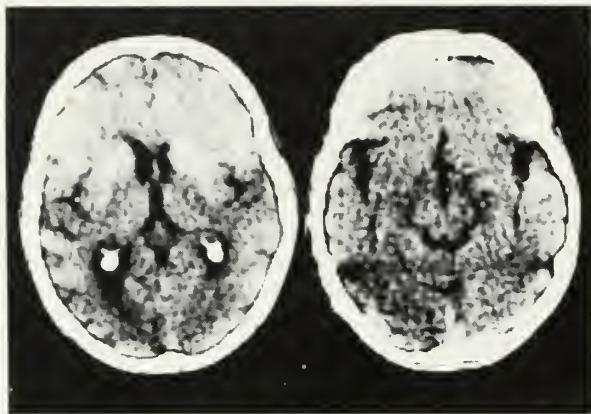


Fig 1. X-ray computed tomographic scan performed two years after onset of illness demonstrates mild atrophy of the left temporal lobe and significant dilatation of the left lateral ventricle.

accurate. When presented with photographs of popular personalities, he could not identify them by name, but could demonstrate recognition by describing their salient personal characteristics. His visual and spatial memory were intact, and he was aware of many current events. A general physical examination was normal, and neurological examination revealed slowing and irregularity of rapid alternating movements performed with the right hand.

Over the next three months his right arm became progressively clumsier, and he lost the ability to use a telephone effectively. He could still follow most commands and insisted that he understood what others said. Quick irregular muscle jerks in his right arm appeared for the first time. A repeat EEG was abnormal because of shifting theta and delta slowing and sharp waves which appeared bilaterally over the frontal and temporal regions, although more so on the left side. The lumbar spinal opening pressure was 180 mm of cerebrospinal fluid, which contained 58 per cent mg protein and no cells.

Non-invasive studies of the carotid circulation were normal. Tests of cerebral blood flow and oxygen utilization demonstrated reduced values over both hemispheres without asymmetries. The Wechsler Adult Intelligence Scale yielded a full-scale score of 90 without significant discrep-

ancies between the aggregate verbal and performance scores. Some variations, however, were observed among the WAIS subtests, especially in the verbal scale. Mental calculations, such as serial sevens, were performed poorly, and his digit span was three forward and two backward. He scored in the defective range on the Wechsler Memory Scale and performed poorly on the Bender-Gestalt, Ravens Matrices, and Benton Visual Retention Tests. There was no apparent visual agnosia.

Although he frequently seemed appropriately despondent over his progressive deficits during the first two years of his illness, his depression gradually lessened and he often seemed inappropriately jocular. His wood-working and gardening skills declined, and he was forced to stop driving because of his increasingly erratic performance. Coordination of his right arm deteriorated as a result of myoclonus. He was vir-

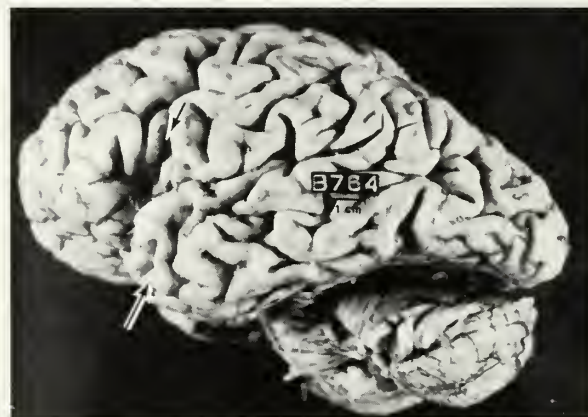


Fig 2. Left lateral view of the brain showing moderate to severe generalized atrophy, accentuated in the temporal lobe (long arrow) and frontal operculum (short arrow).

tually unable to communicate through speech or gestures and auditory comprehension was also impaired. Although he displayed some dexterity, could walk tandem, and exhibited normal muscular tone and down-going toes, he had lost all self-help skills due to apparent apraxia. During the third and fourth years of his illness, myoclonus worsened and spread to all four extremities, while his gait and balance were relatively preserved. He developed a prominent blepharospasm and bilateral grasping. Bowel and bladder function were retained. Tests of thyroid, liver, renal, and bone marrow function remained normal throughout the illness.

When examined by one of us (SP) four years after onset of the illness, the patient, who was

then 59 years old, appeared alert with fluent speech that was completely incoherent. He responded to his name and apparently recognized his wife, but not his sister. He could not properly hold or use a pencil. Snout and suck reflexes were present; he bit the tongue depressor and would not release it. There was generalized myoclonus made worse with intention; deep tendon reflexes were uniformly brisk, and plantars remained flexor. He demonstrated an abnormal gait by walking bent slightly forward and shuffling his feet along the floor, but retained his balance. During the last two years of his life, he developed generalized seizures, which were controlled with appropriate medication, and deteriorated at a more rapid pace. He declined gradually to a vegetative state and died at age 62 of aspiration pneumonia, six years after the onset of his illness.

Neuropathologic Findings

The brain weighed 1108 g. The gross examination after formaldehyde fixation revealed thin, delicate leptomeninges over the cerebral convexities and at the base of the brain. There was no atherosclerosis of the major cerebral vessels. The convolutions of the cerebral hemispheres were moderately to markedly atrophic throughout the brain, especially the temporal poles, and more so on the left side (Fig 2). The left frontal operculum also appeared atrophic or underdeveloped. Coronal sections confirmed more atrophy on the left side and a significantly larger left lateral ventricle (Fig 3). In the most significantly atrophied areas, the cortical mantle was abnormally thin. No abnormalities of basal ganglia, diencephalon, brain stem, or cerebellum were noted during the gross examination.

Paraffin embedded coronal whole brain sections at the level of the amygdala (Fig 3a) and pineal body (Fig 3b) and numerous smaller sections were stained for cells (hematoxylin-eosin, cresyl violet), myelin (Weil and luxol), glial (Holzer) and neurofibrils (Bielschowsky).

There was widespread nerve cell loss and reactive gliosis in the temporal and parietal lobes, especially in supragranular cortical layers II and III. Neuronal loss and gliosis were less apparent in the frontal and occipital lobes, and not evident in the hippocampus and subiculum.

Neuritic plaques and neurofibrillary tangles (Fig 4) were prevalent and their density of distribution generally corresponded to the degree of neuronal loss and gliosis. In the hippocampus and parahippocampal formation, neuritic plaques were found almost exclusively in area

CA1 and adjacent to the rhinal fissure. Neurofibrillary tangles and granulovacuolar changes were observed also in hippocampal pyramids. Nerve cell loss, gliosis, and neurofibrillary tangles were also apparent in the nucleus basalis of Mynert. The cytoplasm of many cortical pyramids and the large neurons of nucleus basalis were often distended with granular yellow pigment compatible with lipofuscin. Ballooned neurons with pale cytoplasm ("Pick cells") and argentophilic intracytoplasmic inclusions ("Pick bodies") were not identified. Neuritic plaques were also densely distributed in the amygdaloid nuclei and neurofibrillary tangles were prevalent in large neurons of the amygdala and ventrolateral hypothalamus. In contrast to these findings, the cytological appearance of the basal ganglia, thalamus, brainstem, and cerebellum was normal. The white matter of the temporal lobes was reduced in volume and abnormally pale in myelin stains (Fig 3), especially adjacent to neocortical areas which exhibited the most severe

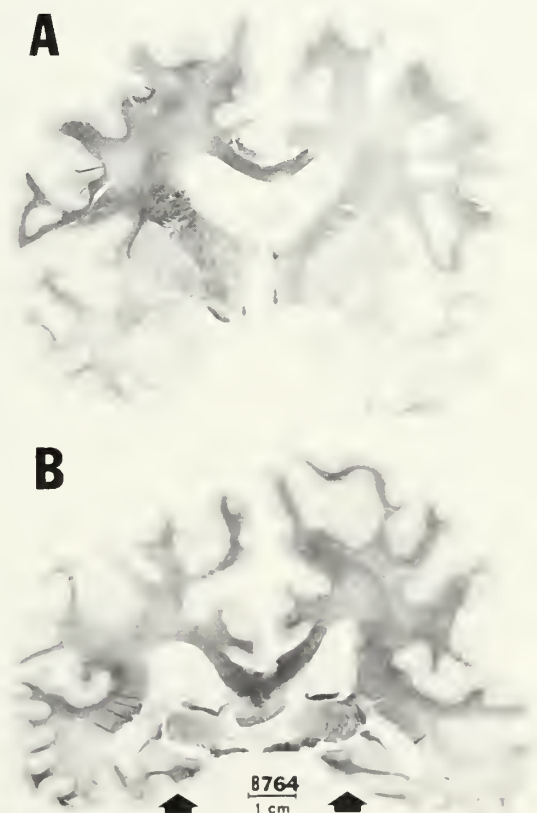


Fig 3. Coronal sections through the amygdala (A) and pineal body (B) showing atrophy of the cerebral hemispheres and enlargement of the lateral ventricles. The atrophic process is more pronounced on the left. The pallor of the white matter under the temporal neocortex with relative sparing adjacent to the parahippocampal gyri is also apparent (arrows) (Weil's stain for myelin).

nerve cell loss and gliosis.

Although rapid Golgi impregnations were attempted, they could not be interpreted because of incomplete neuronal impregnation. Electron micrographs revealed typical paired helical 22-24 nm filaments in neurons of frontal and hippocampal cortex. Neuritic plaques contained neurites distended with paired helical filaments and osmophilic lysosomal inclusions, surrounding a core of 10 nm (amyloid) fibrils.

Discussion

To our knowledge, this is the first reported case of Alzheimer's disease presenting as a fluent aphasia. The language disorder was insidious in onset, was initially an anomic aphasia, and in the first six to twelve months mimicked the angular gyrus syndrome.¹ Dressing and other apraxias, memory impairment, polymyoclonus, and epilepsy subsequently confirmed the widespread nature of the cerebral degenerative disorder. The focal aphasic clinical presentation was matched by asymmetric atrophy of the left temporal lobe and enlargement of the left lateral ventricle, as evident on the first CT scan (Fig 1).

The clinical and radiological features of this case closely resemble those reported by Wechsler et al in a man who was felt on neuropathological study to have Pick's disease.⁵ Wechsler postulates that the combination of slowly progressive posterior aphasia and focal atrophy of the left temporal lobe, as demonstrated by CT scan, might be sufficient to establish a diagnosis of the Pick subtype of presenile dementia. The present case contradicts this hypothesis. Presumably, fluent aphasia may now be added to the list of other focal deficits, such as cortical blindness,^{6, 7} astereognosis,⁸ Gerstman syndrome,^{1, 9} pyramidal,¹⁰ and extrapyramidal^{10, 11} motor disorders as the presenting symptoms in exceptional cases of Alzheimer's disease.

Although the onset of dementia proximate to an episode of head injury is interesting, its significance remains uncertain. Scholarly discussions of the relationship between head injury, either as a single event or repeated episodes, as in boxers, have been published elsewhere.¹²⁻¹⁶

Polymyoclonus is also well recognized as accompanying dementias of the Alzheimer type. In this patient and most other cases of cerebral degeneration, the pathoanatomic basis of myoclonus is unknown. Common to most, if not all, are cellular neuropathologic changes maximally severe in the neocortex. In this case and some cases of subacute spongiform encephalopathy

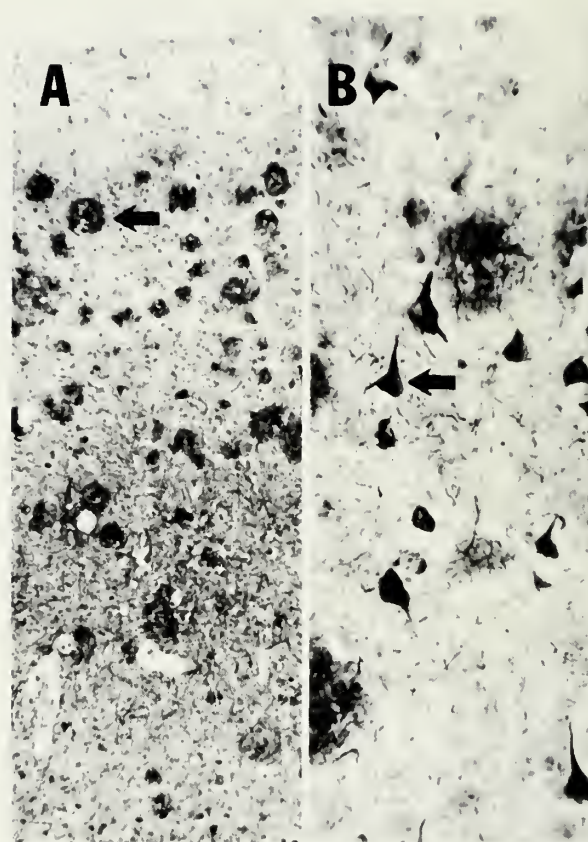


Fig 4. (A) Cortex of the left superior temporal gyrus showing numerous senile plaques (arrow) prevailing in cortical layers two and three (Bielschowsky's stain x 117); (B) Higher magnification showing several neurofibrillary tangles (arrow) (Bielschowsky's stain x 502).

the local circuit neurons and supragranular pyramidal neurons of cortico-cortical association may be involved preferentially.¹⁸ The large layer V pyramidal neurons of subcortical projection (ie, corticospinal, corticobulbar, and corticostriatal) appear to have been relatively spared.¹⁹ It may be plausible to assume that the selective vulnerability of intra- and transcortical association neurons leads to an imbalance of inhibitory and excitatory synaptic inputs, and ultimately to hyperexcitability of layer V pyramids projecting to subcortical motor nuclei.

Conclusion

A 56-year-old man developed a fluent aphasia which progressed for almost one year before other symptoms of a more generalized cerebral degenerative disorder emerged. When aphasia was the most prominent clinical symptom, a CT scan revealed atrophy of the left temporal lobe and enlargement of the left lateral ventricle. The illness progressed to include multiple apractag-

nosias and polymyoclonus, and the patient died in a vegetative state six years later. Neuropathological findings were characterized by widespread nerve cell loss and gliosis in the supragranular layers of the temporal and parietal lobes primarily, coupled with the typical findings of Alzheimer's disease at the light and ultrasonic level. To our knowledge, this is the first case of Alzheimer's disease presenting as a fluent aphasia and confirmed on neuropathological examination.

Acknowledgments

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The Intramuscular Use of Thiothixene in Severely Disturbed and Agitated Patients

Intramuscular Thiothixene Has Proved Valuable In Emergency Situations Involving Such Cases

Manuel E. Soria, MD

The use of high potency neuroleptic drugs for the rapid control of severely agitated patients became common during the early 1970s with the introduction of haloperidol. During the 1960s, chlorpromazine had been used as a neuroleptic. While it was found to produce significant remissions, its administration was at times accompanied by unacceptable levels of sedation and hypotension.^{1, 2} Thiothixene was found in a double-blind study to be as effective as haloperidol to control acutely disturbed and agitated patients.³ The intramuscular administration of thiothixene in controlling acute psychosis was also found to be effective in a psychiatric unit at Wakari Hospital, Dunedin, New Zealand.⁴

The proper use of an effective neuroleptic may be vital, especially during the crises which frequently are encountered at the time of admission. Thiothixene, a thioxanthene derivative which is chemically related to the phenothiazine but differs in the structure of the central tricyclic ring, has been found to be a potent antipsychotic drug and effective in treating acute psychiatric emergencies that require prompt, intensive treatment.

It was the purpose of this retrospective study of severely agitated patients treated at the forensic unit of the Rhode Island Institute of Mental Health to investigate the effectiveness of the intramuscular use of thiothixene.

Methodology

Intramuscular thiothixene was administered to 60 patients who demonstrated severe agitation in

Manuel E. Soria, MD, Clinical Director, Forensic Unit, Rhode Island Institute of Mental Health, Cranston, Rhode Island.

Table 1. — Diagnostic Categories

Diagnosis	Number Of Patients
Schizophrenia:	
Paranoid	12
Catatonic	1
Undifferentiated	10
Disorganized	2
Residual	3
Schizophreniform	4
Brief reactive psychoses	1
Affective disorder:	
Bipolar disorder, mixed	1
Bipolar disorder, manic	3
Schizoaffective	2
Cyclothymic disorder	2
Substance use disorder:	
Mixed	3
Alcohol	2
Personality disorder:	
Borderline	5
Antisocial	7
Antisocial with mental retardation	2

psychotic states. All were males between the ages of 18 and 57 years. The criteria used to indicate the resolution of acutely florid symptoms were documented in the summaries of the psychiatric assessment, treatment plan records, and progress notes for each patient. The disappearance of the florid symptoms was recorded as "improved."

The usual dose was 5 to 10 mg administered parenterally. In some cases, intramuscular injections of thiothixene were repeated every 30 to 60 minutes until the acute agitation had abated. In other cases, a dosage of 5 to 10 mg every four hours was adequate. No more than 60 mg of thiothixene were administered during any 24-hour period. Oral medication was continued as necessary until adequate control was achieved.

A brief clinical evaluation was usually carried out before the initiation of treatment. The diagnostic criteria (Table 1) are outlined in the *Diagnostic and Statistical Manual (3rd Edition)*.

Results

The responses of two separate groups of patients were analyzed. Table 2 summarizes the diagnoses and responses of the first group of 40 patients with no previous admissions. Three patients improved within one day, 17 patients in two days, and 17 patients in three days. Three remained unchanged.

Two of these patients warrant additional consideration. A 40-year-old chronic schizophrenic with moderate mental retardation and a psychosexual disorder had not responded to various neuroleptic medications. The patient displayed an extreme state of agitation and assaultive behavior. The results were dramatic with intramuscular injections of thiothixene administered in dosages of 10 mg hourly and a total dose of 60 mg within the 24-hour period.

The second patient was a 28-year-old male with catatonic features, serial flexibilities, and confusion, who dramatically recovered after three days of treatment with intramuscular thiothixene.

This result is comparable to those achieved with electroconvulsive therapy.

Adverse Reactions

No serious adverse reactions were observed. Some clinicians found relatively greater evidence of extrapyramidal symptoms with thiothixene than with trifluoperazine. Almost all of the patients were given biperiden, which prevented severe undesirable effects. Eight experienced dizziness and drowsiness. A laboratory examination revealed no abnormalities in either the complete blood count or liver function tests.

The 45 patients with a history of previous admissions are listed in Table 3. Large doses of phenothiazine and butyrophenone had been used to control the psychotic states in some of these patients, and others received moderate to large doses of thioridazine. While some of the medications given during the previous admissions have been omitted for the purposes of simplification, most of the patients were treated with multiple neuroleptic agents.

Table 4 compares the results of ten patients treated with thiothixene who had received other neuroleptic drugs during prior admissions. Table 5 summarizes the results of five patients

Table 2. — Response of 40 Patients With No Previous Admissions

Diagnosis	Number of Patients	Improved In 1 Day	Improved In 2 Days	Improved In 3 Days	No Response
Schizophrenia:					
Paranoid	12	1	6	4	1
Catatonic	1	—	—	—	—
Undifferentiated	10	—	1	3	1
Disorganized	2	—	1	—	—
Residual	3	—	1	—	—
Schizophreniform	4	—	2	2	—
Brief reactive psychoses	1	1	2	1	—
Affective disorder:					
Bipolar disorder	1	—	—	—	—
Bipolar disorder, manic	3	1	—	2	1
Schizoaffective	2	—	—	2	—
Cyclothymic disorder	2	—	1	—	—
Substance use disorder:					
Mixed	3	—	1	1	—
Alcohol	2	—	—	—	—
Personality disorder:					
Borderline	5	—	2	2	—
Antisocial	7	—	—	—	—
Antisocial with mental retardation	2	—	—	—	—

(—) No significant change.

Table 3. — Response of 45 Patients with Previous Admissions

Diagnoses	Number of Patients	Improved in 1 Day	Improved in 2 Days	Improved in 3 Days	No Response
Schizophrenia	15	2	5	7	1
Schizophreniform	2	—	1	1	—
Affective disorder:					
Bipolar disorder:					
Mixed	—	—	—	—	—
Manic	10	—	3	6	1
Depressed	—	—	—	—	—
Schizoaffective	3	—	—	2	1
Cyclothymic	2	—	1	1	—
Substance use disorder:					
Mixed and alcohol	5	1	3	1	—
Personality disorder:					
Borderline	—	—	—	—	—
Antisocial	8	—	4	4	—
Antisocial with mental retardation	—	—	—	—	—

with varied diagnoses and compares the efficacy of thiothixene to prior treatment.

Discussion

The therapeutic value of parenteral thiothixene has been demonstrated in a number of studies. Studies of the intramuscular administration of thiothixene in acutely schizophrenic patients has proven its effectiveness.⁶ Braurer and Goldstein compared the efficacy of thiothixene administered parenterally in a double-blind study and concluded that thiothixene is as effective as trifluoperazine.⁷ A study by Filotto revealed the effectiveness of oral thiothixene for treating manic patients,⁸ and preliminary reports of the beneficial effects during the depressive phase of bipolar depression are beginning to appear in the literature.

In the forensic unit where this study was conducted, psychosis induced by psychedelic drugs is often encountered. Thiothixene appears to be the treatment of choice to control the psychotic states produced by these hallucinogens. Phenothiazine is known to precipitate cardiovascular disturbances.

Conclusion

This retrospective study has demonstrated that thiothixene is highly effective in controlling severely agitated and psychotic patients. It can be recommended for use in closed, as well as open, hospital wards. The use of seclusion and restraints may be reduced with the parenteral use of thiothixene. It also can be used in emergency situations occurring in private practice.

Table 4. — Comparison of Treatments: Schizophrenia (Paranoid and Undifferentiated Type)

Patient Number	Improvement in Days With Prior Treatment	Improvement in Days With Thiothixene Treatment
1	12	3
4	20	4
6	14	4
9	12	5
10	15	4
11	12	3
14	7	2
36	14	2
40	10	2
60	10	2

Table 5. — Comparison of Treatments

Patient Number	Diagnosis	Improvement in Days With Prior Treatment	Improvement in Days With Thiothixene
3	Chronic, undifferentiated schizophrenia	7	4
25	Substance use disorder, mixed	7	2
37	Substance use, LSD	10	2
38	Substance use, alcohol	5	2
59	Personality disorder, anti-social	6	3

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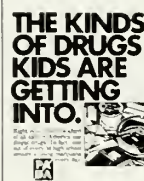
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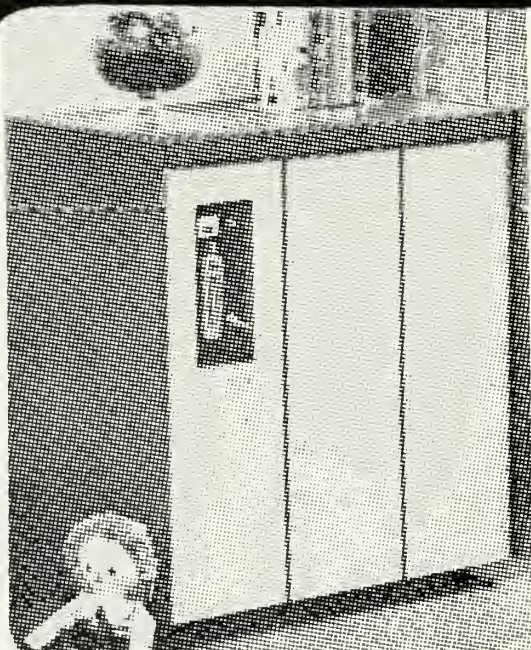
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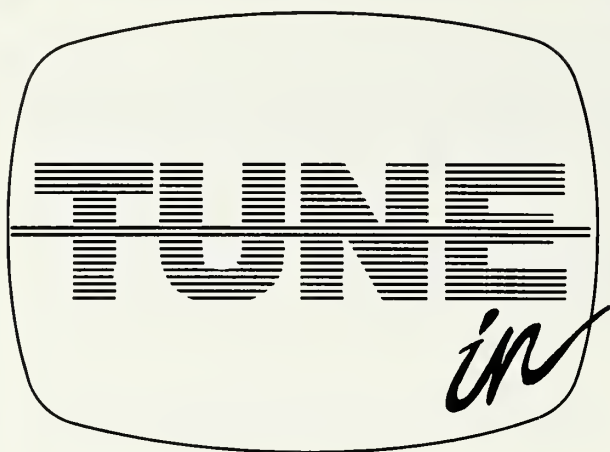
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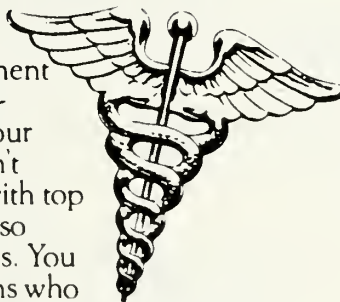
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The General Electric Company recently introduced the RTP® pedestal table with a four-way float top for routine radiography, and trauma and orthopedic examinations. The table will accommodate patients weighing up to 300 lbs, and a special four-way shift reduces handling of the patient. The table top also is specially constructed to reduce absorption of radiation and includes such features as accessibility from all sides, patient hand grips, and nonprotruding edge rails.

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• • •

The Robert Wood Johnson Foundation recently announced a national study to evaluate the effectiveness of services intended to reduce the incidence of health and developmental problems among low birthweight infants. Dramatic declines in infant mortality since 1900 have resulted, to a large extent, from increasing success in keeping small babies alive. Infants weighing less than 5.5 lbs at birth are more vulnerable to illness and disability than larger infants. The Foundation will award grants of up to \$1.83 million each to six medical schools and teaching hospitals over a period of four years.

Infants will be randomly assigned to one of two treatment groups at each of the six sites. While infants in both groups will receive continuing medical care, those in one of the groups will receive special child developmental services both in the home and in a child developmental center while the others will not. In this way, the program hopes to evaluate the impact of the two types of services and determine their value for low birth-weight infants.

• • •

The *Saturday Evening Post* and the Benjamin Franklin Society have announced a \$5,000 cash award for the report that best motivates the general public to add fiber to their diets. The Society hopes to encourage many writers to complete stories for their newspapers, magazines, house organs, neighborhood newspapers, and church publications that will present a detailed analysis of fiber and its effects. The grant will allow the winner to visit a foreign country to study dietary customs and food preparation. For additional information write Cory SerVaas, MD, Benjamin Franklin Society, 1100 Waterway Boulevard, Indianapolis, Indiana 46202.

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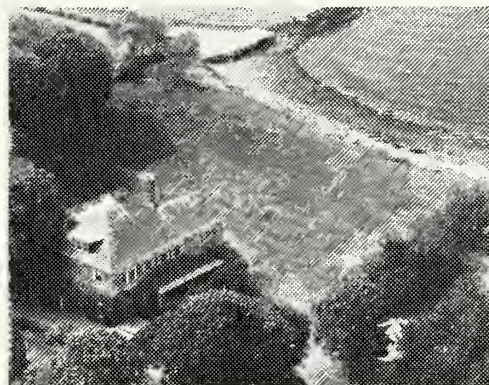
The Raytheon Company has developed a new digital x-ray imaging system which, according to company officials, will "dramatically change the way physicians can perform diagnostic angiography." The new system uses a specially designed high-speed computer to produce five times as many images per second time than available from the most advanced equipment currently on the market. It can capture 30 x-ray images per second to provide a more precise diagnostic method of detecting vascular blockages and capturing arterial motion on film. Moreover, the injection of contrasting dye may now be made in a vein rather than in an artery as required with conventional angiographs, and may well result in a reduced hospital stay and less risk for most patients.

• • •

According to a report in the November 1983 issue of *American Journal of Diseases of Children*, infants least likely to be provided with protective automobile child restraint seats have parents who are not married to each other, who never finished high school, and who rarely use seatbelts themselves. Researchers from the Borgess Pediatric

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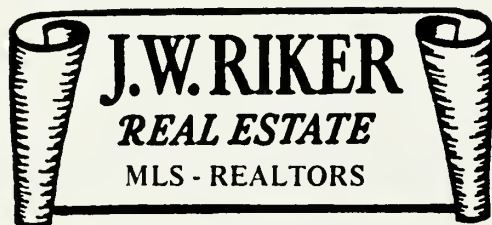
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Center in Kalamazoo, Michigan also cite other indicators of lack of child restraint use: when family income is under \$15,000, both parents are smokers, and maternal awareness of pediatric preventive medicine principles is lacking. Hospitals are encouraged to establish special educational programs targeted towards this group of parents to help reduce auto fatalities among infants and small children.

• • •

Researchers at the University of Alabama Medical School recently reported on the successful management of 50 patients with colorectal carcinoma metastatic to the liver who were treated with a totally implantable drug infusion pump. The report, published in a recent issue of the *American Journal of Surgery*, notes that only 15 to 20 per cent of patients respond to treatment with 5-fluorouracil, even when it is administered in combination with other drugs.

The infusion pump, developed by Infusaid Corp of Norwood, Massachusetts, is powered by charged freon, has a chamber capacity of 50 ml, and a fixed rate of 3 ml/day. The pump is silent, small (10 by 3 cm), and lightweight (180 g). It is refilled and automatically recharged by a simple percutaneous injection through the skin every two weeks. The pump is connected to a Silastic® catheter placed in the gastroduodenal artery up to the lumen of the hepatic artery.

An objective remission was induced in 83 per cent of the cases as demonstrated by a decrease in their carcino-embryonic antigen levels by a mean of 80 per cent. These remissions were confirmed by liver sonograms which showed either stable or decreased tumor volume. There was little or no systemic toxicity, such as vomiting, diarrhea, or marrow suppression. The report emphasizes the preliminary nature of the findings, but notes that an implantable infusion pump system is "technically feasible, safe, and capable of inducing a remission in most patients with colorectal metastases."

• • •

The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) now makes direct payments to nurse practitioners. According to the CHAMPUS Information Office, the program has been paying nurse practitioners directly since May 1980, when Congress authorized an experimental study. Before then, nurse practitioners could receive CHAMPUS reim-

bursement only if they provided care under the supervision of a physician.

Under the Defense Appropriation Act of 1983, however, a certified nurse practitioner may provide CHAMPUS-covered services without the referral or supervision of a physician if he or she is a registered nurse licensed or certified as a nurse practitioner in the state where care is provided. In states (such as Rhode Island) which do not offer certification or licensure, nurse practitioners must be certified by the American Nurses Association.

• • •

The families of a terminally-ill child will fare better emotionally and psychologically if the child is allowed to die at home rather than in a hospital, according to a report in the May 1983 issue of *Pediatrics*, the journal of the American Academy of Pediatrics.

The Midwest Children's Cancer Center at the Medical College of Wisconsin and Milwaukee Children's Hospital conducted a series of studies which suggest fewer adjustment problems result for families who have participated in a formalized home care program for dying children. Parents of patients who died in the hospital were more anxious, depressed, and defensive, and had greater tendencies towards physical and interpersonal problems than parents of patients in the home care program. Siblings of patients who received hospital terminal care were more emotionally inhibited, withdrawn, and fearful than their counterparts in the home program.

• • •

Routine preoperative chest x-ray films of children should not be required since films should be ordered only at the discretion of the attending physician, according to a recommendation of the American Academy of Pediatrics (AAP).

The Academy's Committee on Hospital Care maintains that routine x-ray studies identify few unsuspected significant diseases among children. Chest x-ray films should not replace a complete medical history and physical examination, which remain the best means of determining those patients who run a risk of complications during surgery. Preoperative chest x-rays may be necessary when either the history or physical findings indicate respiratory, cardiovascular, chronic renal, immune deficiency, or certain hematologic diseases, or malignant tumors with possible pulmonary involvement.



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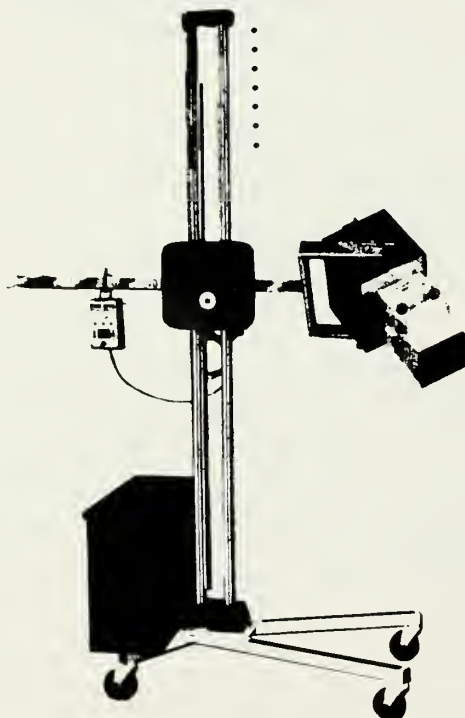
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Treatment of physicians for alcohol addiction shows a favorable outcome in 83 per cent of cases, and treatment of physicians for drug addiction has a 95 per cent success rate. More than 70 per cent of the physicians entering treatment return to the active practice of medicine.

The Rhode Island Medical Society Committee on Impaired Physicians, chaired by Dr Herbert Rakatansky, meets monthly. It is a standing committee of the Society charged with "helping physicians whose professional judgments and capabilities are impaired by their difficulties with chemical dependency or other illnesses."

The Committee handles inquiries in *complete confidence*. If you know of a physician who needs an advocate and support in obtaining necessary treatment, please call or write Dr Rakatansky c/o The Committee on Impaired Physicians, Rhode Island Medical Society, 106 Francis Street, Providence 02903 (401/331-3207).

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Inspiring plans have been developed to restore the Statue and to create on Ellis Island a permanent museum celebrating the ethnic diversity of this country of immigrants. But unless restoration is begun now, these two landmarks in our nation's heritage could be closed at the very time America is celebrating their hundredth anniversaries. The 230 million dollars needed to carry out the work is needed now.

All of the money must come from private donations; the federal government is not raising the funds. This is consistent with the Statue's origins. The French people paid for its creation themselves. And America's businesses spearheaded the public contributions that were needed for its construction and for the pedestal.

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References: 1. Kales J et al: *Clin Pharmacol Ther* 12:691-697, Jul-Aug 1971. 2. Kales A et al: *Clin Pharmacol Ther* 18:356-363, Sep 1975. 3. Kales A et al: *Clin Pharmacol Ther* 19:576-583, May 1976. 4. Kales A et al: *Clin Pharmacol Ther* 32:781-788, Dec 1982. 5. Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. 6. Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. 7. Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther* 21:355-361, Mar 1977. 8. Zimmerman AM: *Curr Ther Res* 13:18-22, Jan 1971. 9. Amrein R et al: *Drugs Exp Clin Res* 9(1):85-99, 1983. 10. Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. 11. Greenblatt DJ et al: *Sleep* 5(Suppl 1):S18-S27, 1982. 12. Kales A et al: *Pharmacology* 26:121-137, 1983.

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Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, light-headedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

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Medical Journal

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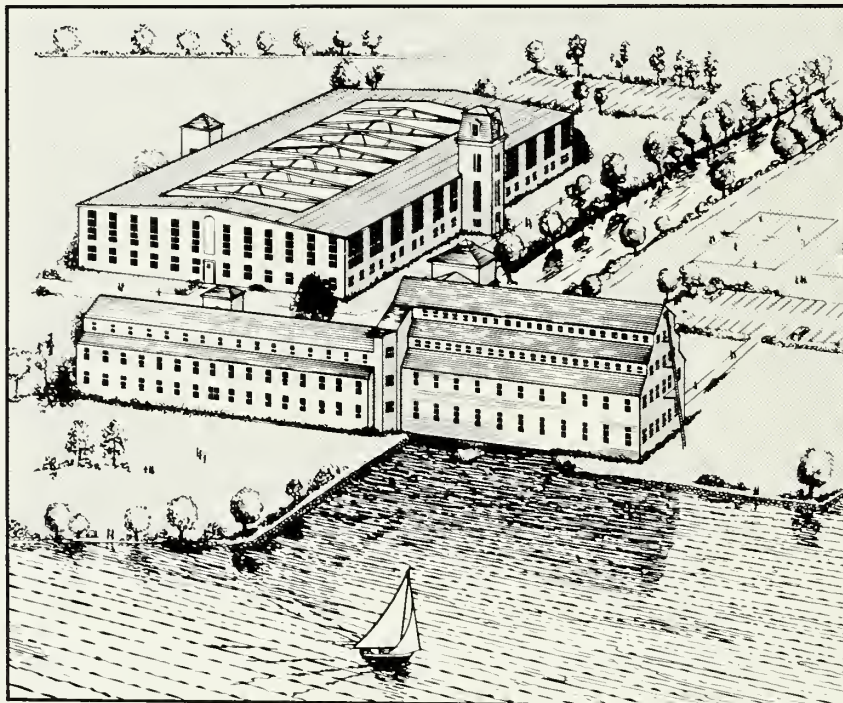
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Newsletter

RHODE ISLAND MEDICAL SOCIETY

May 1984

Charles P. Shoemaker, Jr., MD, President
Wendy J. Smith, Editor

COUNCIL ADDRESSES REIMBURSEMENT PROBLEMS WITH THE BLUES

The Council recently directed President Dr Charles P. Shoemaker, Jr., to write Blue Cross & Blue Shield of Rhode Island and two state agencies concerning members' recent problems with the carrier. The action was taken at the Council's April 3 meeting in response to increasing concerns of members about delayed and reduced payments from the Blues. The problems reportedly stem from administrative difficulties resulting from the Blues' acquisition of a 17-state CHAMPUS contract late last year.

As the result of Federal Trade Commission (FTC) actions in other states, the Society severed its relationship with the local Blues plan in 1982. Legal counsel John A. Reid, III, however, told the Council that there were no legal constraints against the Society's sending a letter to Blue Cross & Blue Shield as an expression of membership concern. The Council also encouraged individual physicians to write the Blues, the Rhode Island Attorney General, and the Director of Business Regulation.

Letters should be sent to:

Douglas J. McIntosh, President
Blue Cross & Blue Shield of Rhode Island
444 Westminster Mall
Providence, Rhode Island 02901

The Hon. Dennis J. Roberts, II
Attorney General
250 Benefit Street
Providence, Rhode Island 02901

William F. Carroll
Director
Department of Business Regulation
100 Main Street
Providence, Rhode Island 02903

ANNUAL MEETING SCHEDULED FOR MAY 23

RIMS President Dr Charles P. Shoemaker, Jr. recently extended a personal invitation to

ANNUAL MEETING (continued)

all Society members to attend the 173rd Annual Meeting, Wednesday, May 23, 1984, at the Providence Marriott Hotel.

Highlights of the meeting include:

- An informative and stimulating luncheon session scheduled for members of the House of Delegates and the Council with Dr Joseph F. Boyle, President-Elect of the American Medical Association. The annual session of the House of Delegates will follow the luncheon.
- The 1984 Chapin Oration to be presented by Dr Robert G. Petersdorf, a respected infectious disease specialist and accomplished administrator. Petersdorf currently is Vice-Chancellor for Health Sciences and Dean of the Medical School, University of California at San Diego. In his invitation, Dr Shoemaker said, "Dr Petersdorf promises to deliver some fresh insights on the perennial problem of government and medical practice."
- An opportunity to shape the Society's agenda for the next year at the annual business meeting. The meeting will feature the 1984 Presidential Address and the installation of the 1984-1985 officers: Drs Paul J.M. Healey, President; Leonard Staudinger, President-Elect; Melvyn M. Gelch, Vice-President; Milton W. Hamolsky, Secretary; and Kenneth E. Liffmann, Treasurer.

The Annual Dinner, starting at 5:30 pm with a brief reception, will be a social affair with entertainment by the Nightscene. Two members will be recognized at the dinner for their contributions to the Rhode Island medical community. Dr. Henry T. Randall, Surgeon-in-Chief Emeritus, Rhode Island Hospital, will receive the Charles L. Hill Award for Distinguished Service. The Society also will recognize Dr Joseph E. Cannon, who will retire in July after 23 years as

Director of the Rhode Island Department of Health.

Registration forms were sent to all RIMS members in late April. Members who have not made their reservations should call Edwina L. Rego at 401/331-3207.

COUNCIL APPROVES REVISED STATEMENT ON MEDICAL RECORDS

The Council of the Rhode Island Medical Society recently approved a revised version of the position statement, "Rhode Island Physicians and Medical Records," which originally was developed by the Society and the Board of Medical Review in October 1982. It was designed to provide members with a convenient summary of the applicable state laws covering medical records. The changes were suggested to forestall the introduction of proposed legislation which would mandate that medical records are the property of the patient rather than the physician. After the Board of Medical Review approves the revisions, a new printing will be sent to all RIMS members.

In other actions at its April 3 meeting, the Council:

- authorized E. James Stergiou of the New York actuarial consulting firm Woodward & Fondiller to represent the Society at the pending Department of Business Regulation hearings on a proposed malpractice premium hike. The Joint Underwriting Association (JUA) is seeking a 44.6 per cent increase for basic coverage during the 1984-1985 premium year.
- endorsed a child health plan developed by the Rhode Island chapter of the American Academy of Pediatrics. The project originally started in response to various health plans developed by the Statewide Health Coordinating Council. Copies of the plan, which represents three years of work by the specialty society, have been sent to all Rhode Island pediatricians and interested family physicians.
- endorsed a request from the RIMS Committee on the Impaired Physician for

a cash grant from the Joint Underwriting Association. The committee is charged with "providing aid and assistance to physicians whose professional judgments and capacities are impaired by their difficulties with chemical dependencies or other illnesses." The grant is to be used to fund such committee activities as the collection of urine specimens, laboratory testing, and psychological evaluations. These expenditures often are necessary as physicians may be reluctant to use their medical coverage to seek help.

- approved a report from Society President Dr Charles P. Shoemaker, Jr. regarding RIMS liaison activities with the Brown University Program in Medicine. RIMS officers met recently with Brown administrators and faculty to discuss such problems as physician supply, the Brown residency programs, pending legislation, and physician's assistants. Future meetings are planned.
- heard from Dr Shoemaker and President-Elect Dr Paul J.M. Healey about their meetings in late March with the Rhode Island Congressional delegation to discuss pending federal legislation which would mandate acceptance of Medicare assignment. The series of Washington, DC meetings was organized by the AMA. During the sessions, the RIMS officers said that physicians are concerned about the financial stability of the Medicare program, but stressed that any long-term solutions must include substantive legislative efforts to stem the rising costs of malpractice insurance.
- received a report from Nancy Alonso, volunteer coordinator of the Tele-Med program. Instituted in 1975, Tele-Med is a telephone tape system designed to supplement the patient education efforts of physicians and their staffs. Underwritten by the Rhode Island Department of Health, the service receives approximately 200 calls daily from the public.

STAFF APPOINTMENT ANNOUNCED

Society Executive Director Dr Norman A. Baxter recently announced the employment of Dr Newell E. Warde as Assistant Executive Director. Warde, who joins the

Society's staff on June 15, will be responsible for monitoring legislative developments and providing staff support for continuing RIMS activities. He replaces Brian R. Clarke who left the Society in March to accept a position with Blue Cross & Blue Shield of Rhode Island.

Currently assistant professor of German at Bates College in Lewiston, Maine, Warde received his undergraduate degree from Hamilton (NY) College and completed his doctoral training at the University of Massachusetts in Amherst. A native of Schoharie, New York, he has been associated with Bates College since 1977.

CARDIAC DISEASE STILL LEADING CAUSE OF DEATH

While cardiovascular disease continued as the leading cause of death in Rhode Island, the mortality rate for three other conditions increased dramatically during the first nine months of last year. Nearly 2,800 Rhode Islanders died from cardiac disease during the period under consideration. According to preliminary figures from the Rhode Island Department of Health, deaths resulting from pneumonia and influenza during the period January-September 1983 rose by nearly 50 per cent when compared to the same period in 1982.

Significant increases also were seen in the mortality rates for atherosclerosis (32.4 per cent) and chronic obstructive pulmonary disease (16.6 per cent). Deaths resulting from chronic liver disease and cirrhosis decreased by slightly more than 10 per cent.

AMA SEEKS INFORMATION ON DRGs

The American Medical Association launched a new program to monitor physicians' experiences with the recently-implemented prospective payment system for Medicare inpatients. By the end of this year, most hospitals participating in the Medicare program will be reimbursed on a flat rate according to the diagnosis-group (DRG) payment methodology.

The organization plans to use physician reactions as one of the bases for recommending changes in the DRG system to Con-

gress and federal agencies. While all relevant experiences are of interest, the AMA specifically is seeking information concerning the following: cost and quality of care, length of stay, impact on hospital admissions and discharge policies, medical staff relationships with hospital administration, and utilization review.

Physicians are encouraged to describe their experiences with DRGs, both positive and negative, in a brief letter and send it to:

DRG Monitoring Project - AMA
Department of Health Care Resources
PO Box 10947
Chicago, Illinois 60610

PERIPATETICS

Society members in the news include:

- Dr Peter L. Mathieu, a Providence pediatrician, has been appointed to the Statewide Health Coordinating Council. Dr Mathieu served as the Society's president during 1980-1981.
- Another RIMS past president, Dr Joseph E. Caruolo, was elected to his second one-year term as SHCC chairman in March.
- Dr Barry L. Levin, a Providence neurologist, has been named chairman of the medical advisory committee of the Rhode Island Chapter of the Multiple Sclerosis Society.
- The American Academy of Orthopaedic Surgery recently inducted as fellows Drs Leonard F. Hubbard, Providence, and Frederick M. Johnson, Johnston.
- Dr Y Jacob Schinazi, Providence, was installed as president of the Rhode Island Ophthalmological Society. Other officers include Drs Harold Woodcome, Jr., President-Elect; and Elliot Perlman, Secretary-Treasurer.
- And in the arts news . . . Dr Yusef Barcohana, Providence, placed second in the sculpture division at the 1983 American Society of Anesthesiologists Annual Meeting art exhibition.

THROUGH THE MEDICARE MAZE -- HOW ARE DRGs ASSIGNED?

Effective October 1, 1983, reimbursement for most hospitalized Medicare patients is based on the assignment of a diagnosis-related group (DRG) instead of the traditional payment method based on the actual costs of providing medical care. Because the DRG system already has affected the hospital practices of many physicians, a familiarity with its functioning is essential. Moreover, Congress presently is considering several bills which would apply the DRG methodology, known generically as a prospective payment system, to all patients regardless of the source of their insurance coverage.

What information is needed to assign a DRG?

Six pieces of data are necessary to assign a hospital case to the appropriate DRG:

- The principal diagnosis is the one established after the patient workup as the primary reason for the hospital admission.
- Any secondary diagnoses must be classified as either comorbidities (concomitant conditions existing at the time of admission) or complications (conditions which developed after admission).
- The procedures include the diagnostic and therapeutic procedures performed.
- Age and sex of the patient
- The discharge status is recorded as one of the following: routine discharge to home, discharged against medical advice, transferred to another facility, or deceased.

The International Classification of Disease (ICD-9-CM) is used as the primary coding mechanism for both principal and secondary diagnoses and for procedures. The hospital medical records staff often must ask the attending physician for additional specific information to determine which of the 13,000 codes in the manual should be assigned to a case. The problem is further complicated by the fact that not all of these codes are considered to be acceptable comorbidities or complications.

How are DRGs actually assigned?

The assignment process consists of five separate stages: On admission, the medical record is initiated with the following information: age, sex, admission date; admission diagnosis; and comorbidities, if any. After the patient workup, the record should include the diagnostic procedures performed and the presence of any additional diagnoses or comorbidities. After treatment, the record must detail all therapeutic procedures and any complications. At discharge, the discharge status of the patient is determined and recorded, the final diagnosis established, and the discharge date noted.

After discharge, all information is translated into ICD-9-CM codes by the medical records staff, and the length of stay is calculated. When all applicable data have been entered into the record, Medicare requires that the attending physician attest to the accuracy of the information. This may occur either before after the coding process.

NEXT MONTH: *What is an "outlier?"*

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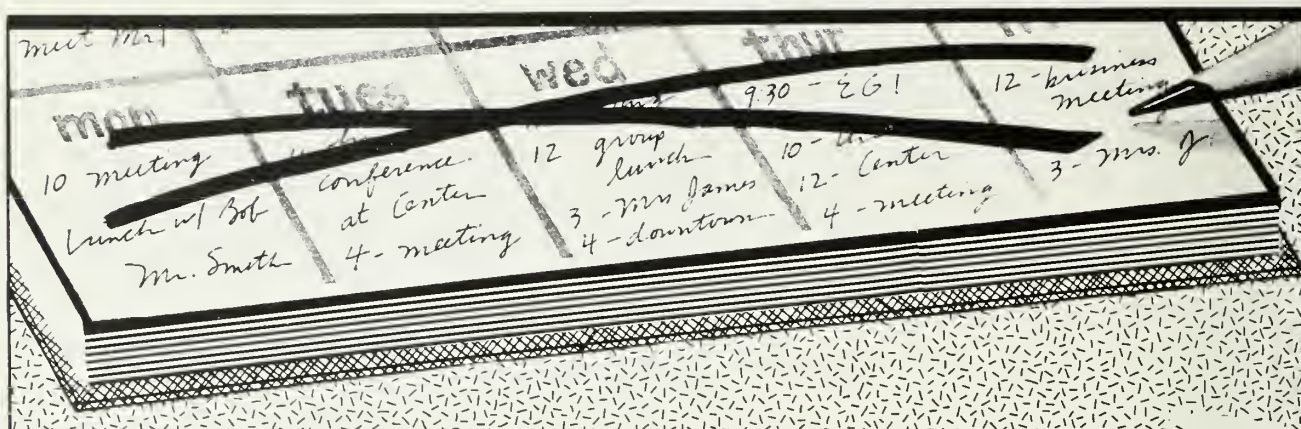


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May 1984
Volume 67, Number 5

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Apparently Unrelated Symptoms May Be Manifestations of the Same Disease Process

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A physical therapist at The Miriam Hospital Chronic Pain Treatment Program administers therapy to a patient suffering from chronic low back pain. The dysfunction has been called "one of the most expensive, difficult, and prevalent problems facing medicine." For more on chronic pain and the rehabilitative approach followed at The Miriam Hospital, see page 219.

Photograph by Gene Dwiggins, courtesy of The Miriam Hospital, Providence, Rhode Island.



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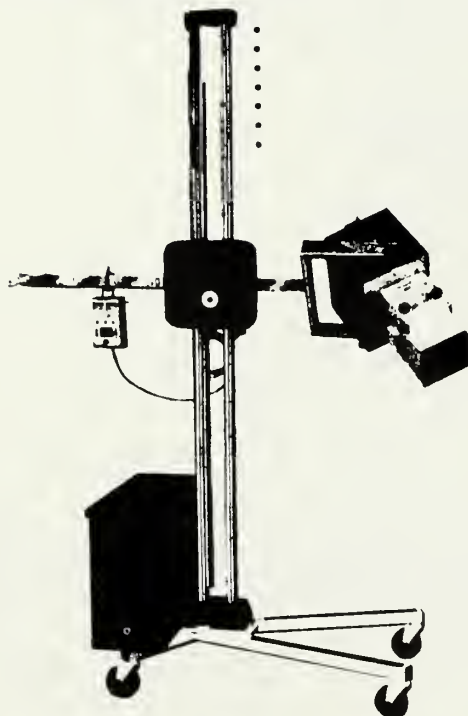
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The Rhode Island Medical Society Committee on Impaired Physicians, chaired by Dr Herbert Rakatansky, meets monthly. It is a standing committee of the Society charged with "helping physicians whose professional judgments and capabilities are impaired by their difficulties with chemical dependency or other illnesses."

The Committee handles inquiries in *complete confidence*. If you know of a physician who needs an advocate and support in obtaining necessary treatment, please call or write Dr Rakatansky c/o The Committee on Impaired Physicians, Rhode Island Medical Society, 106 Francis Street, Providence 02903 (401/331-3207).

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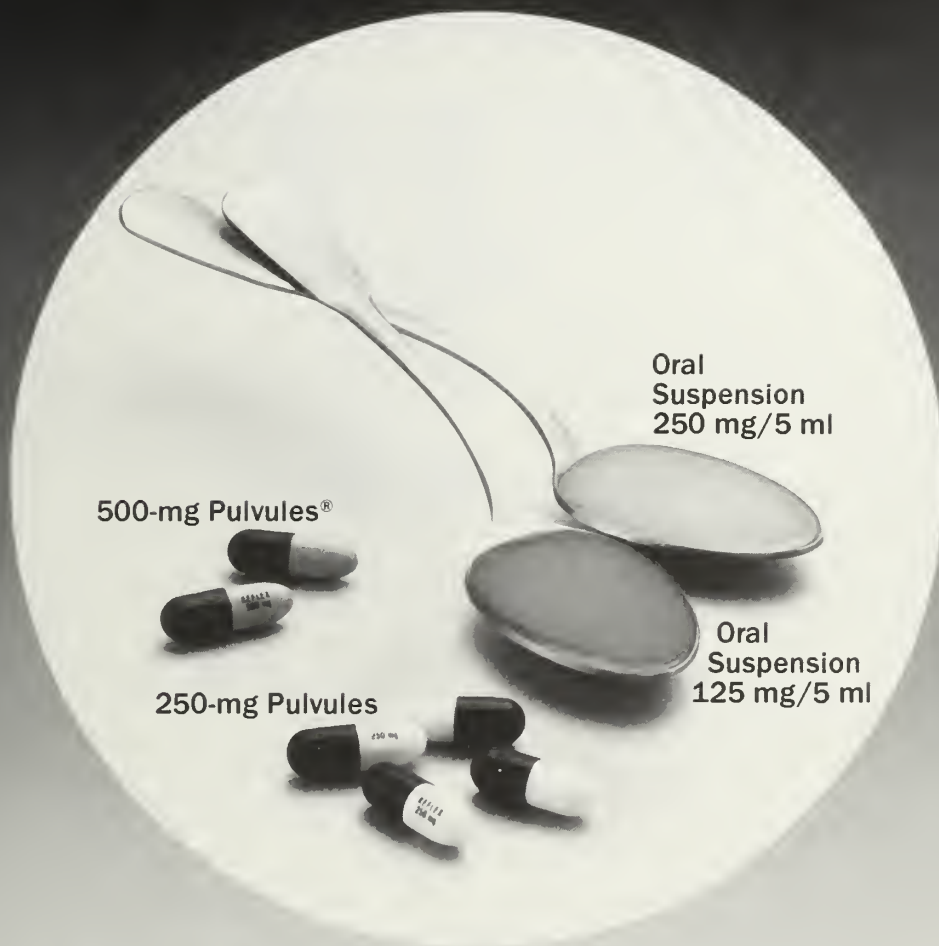
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The Medicare Assignment Option: The Debate Intensifies

May is "Older Americans Month," a time officially designated to focus attention on the social, economic, and medical issues facing the elderly. This month it is especially fitting that Medicare, a program which affects most older Americans, continues to receive considerable attention from the medical and popular press. As legislative debates on the fiscal soundness of the program intensify, it is likely that there will be more controversy over one aspect of Medicare reimbursement, the so-called "assignment of Medicare benefits." Within the past six months, we have seen the introduction of four legislative proposals on the federal level and one resolution in the Rhode Island General Assembly which would require physicians to accept assignment of Medicare benefits as "payment in full."

The subject is an emotionally-charged one for both physicians and their older patients. At the center of the debate is the issue of whether physicians may bill their Medicare patients more than the fee paid by the federal government for that particular service. Physicians currently may choose on a case-by-case basis whether to assign the claim. In either case, Medicare will pay only 80 per cent of its allowed fee. In a phrase especially galling to many physicians, this fee allowance is described in Medicare terminology as the "reasonable charge." If the claim has been assigned to the physician, the patient is responsible for a 20 per cent copayment. For unassigned claims, the Medicare beneficiary must pay both the copayment and any difference between the physician's charges and the Medicare fee allowance.

The assignment rate, or the percentage of times that physicians accept the Medicare fee allowance as payment in full, has decreased steadily since the late 1960s. On a national average, physicians in 1969 accepted assignment for 61.5 per cent of all Medicare claims filed. By 1980, that figure had dropped to 51.5 per cent and in 1982

to 42 per cent. However, these national statistics are slightly misleading since the assignment rate varies widely throughout the country. In 1982, it ranged from a high of 82 per cent in Rhode Island to 19 per cent in Wyoming. Despite the high assignment level in this state, there is growing worry among the elderly about the burden of out-of-pocket expenditures for medical care. As a reflection of this concern, the Rhode Island General Assembly recently approved a resolution calling upon the US Congress to require that physicians accept assignment for their Medicare patients.

At the time of this writing, Congress was considering several bills which would mandate assignment. The House Ways and Means Committee has approved a proposal which would freeze Medicare fees for one year and require assignment of all inpatient claims. While a plan approved by the Senate Finance Committee would not mandate assignment, it would extend a proposed one-year freeze on Medicare payments for physicians who did not "voluntarily" accept the federal reimbursement. There are variations on each of these major proposals, and other options under consideration as well. It has been suggested that assignment be required for office visits and other outpatient services, and that physicians either accept all claims or none at all. The Kennedy-Gephardt bill would extend the reimbursement system based on diagnosis-related groups (DRGs) to outpatient services. A less coercive recommendation is designed to encourage physician participation in the program by offering a simplified billing procedure to those who accept assignment.

One bill has especially ominous implications for physicians and hospitals. Introduced by House Aging Committee Chairman Edward Roybal (D., California), the proposal would prohibit physicians from charging their elderly patients for the difference between their profes-

sional charges and the Medicare fee allowance. Unlike other Congressional recommendations, it would require hospitals to deny staff privileges to any physician who refused Medicare assignment. During a press conference held to generate support for the bill, Roybal alleged that physicians "overcharged" Medicare patients by \$2.5 billion last year, or \$107 per patient. While the measure is not given any serious chance of passage this year, it has received the backing of such powerful senior citizens groups as the American Association of Retired Persons and the National Council of Senior Citizens.

The fiscal implications of the Medicare assignment issue are tremendous. Estimated to reach \$25 billion in 1985, the Medicare expenditure for physician services will become the third largest domestic program, exceeded only by Social Security and the Medicare hospital insurance program. According to a staff report prepared for the US Senate Committee on Aging, payments from the Medicare program represent approximately 18 per cent of average gross receipts for physician practices. The report contends that Medicare reimbursement has become "too large a factor" for most physicians to refuse to participate in the program.

Concerns have been raised, however, that mandatory assignment would trigger defections from the Medicare program and result in a two-tiered system of medical care. In testimony before the US Senate Committee on Aging, Doctor James S. Todd, representing the AMA Board of Trustees, maintained that the current assignment option is "an important factor that has enabled physicians

to treat Medicare patients in the same manner as other patients." Rhode Island Medical Society President Doctor Charles P. Shoemaker, Jr., testifying before the Statewide Health Coordinating Council and the Health, Education, and Welfare Committee of the Rhode Island House of Representatives, voiced similar reservations. Moreover, Doctor Shoemaker told both groups, it is apparent that physicians are getting caught in a bind between frozen reimbursement rates and such skyrocketing practice costs as malpractice insurance premiums, higher personnel costs, and increased overhead.

It is unlikely that mandatory assignment would have a significant impact in Rhode Island, he added, because of the already high level of acceptance on a voluntary basis. The recently-published *Guide to Physician Services* indicates that most members of the Rhode Island Medical Society already accept Medicare assignment.

One of the reasons for the emotional intensity that has characterized the debate over the mandatory assignment proposals may be due to the fact that we are confronting what amounts to a broken promise. During the discussions which preceded the enactment of Medicare in 1965, elderly Americans were told that the Social Security program would take care of their medical expenses. For their part, physicians were assured that they would continue to receive their "usual, customary, and reasonable" fees for providing services to Medicare beneficiaries. Neither promise was possible in the face of the limited resources available, and we now must deal with the painful process of readjusting our expectations.

Wendy J. Smith

PRESIDENT'S PAGE



The Year in Review

As the Annual Meeting approaches, it is perhaps fitting to look at the Society's accomplishments during the past year and some of the remaining problems. Generally, organized medicine must spend a considerable amount of effort in reacting to political forces. While the Society had its share of defensive reactions this year, we did take some positive steps to shape the future of medical practice.

We had the first taste of reality last summer when the Society was invited to a conference for the business community on health care costs, which was organized by the Governor's office. Although the program listed an impressive group of economists, business leaders, and other experts, there were no physicians included as speakers. At the Society's instigation, the conference organizers did invite Doctor James K. Davis, Vice-Speaker of the AMA House of Delegates and a recognized authority on cost containment.

Because the Greenhouse Compact demanded so much of the business community's attention, a business coalition to curb rising medical costs has yet to materialize in Rhode Island. In Massachusetts, however, several active business coalitions have emerged. As they quickly recognized that rising malpractice premiums are adding to the costs of medical care, these groups of business leaders have become useful allies in seeking substantive tort reform.

An important event of the year was the Society's November 30 conference on the legislative, economic, and social aspects of medical practice. Nearly 40 physicians, identified by their colleagues as future leaders, attended the day-long invitational meeting. Many of them expressed concern about the impact of a "physician glut." Coincidentally, the *Providence Journal* that day had published a report of plans by the Brown University Program in Medicine to add 33 full-time faculty. There presently are more than 400



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residency positions in the Brown system. As a result, the Society initiated a series of productive discussions with Brown concerning the problems created by an oversupply of physicians. Continuing meetings are planned and a liaison committee will study the physician glut in Rhode Island.

A paradox of this situation recently came to my attention after our local hospital lost the services of several anesthesiologists. The "physician glut" does not apply equally to all specialties as there has been a recent loss of anesthesiologists and other physicians from the state. Several hospitals in Rhode Island lack complete anesthesia coverage. While we pride ourselves on our high level of Medicare assignment, the hard reality is that reimbursement levels for Medicare and other third-party programs may be inadequate to attract and retain some badly-needed specialists.

The liaison committee of the Society and the Rhode Island Bar Association demonstrated considerable foresight by revising the inter-professional code originally developed in 1976. The liaison committee also plans to continue tackling the difficult problem of "do not resuscitate" orders.

During its recently-ended session, the Rhode Island General Assembly considered many bills which would affect both physicians and their patients. Three proposals are especially noteworthy. With the Society's assistance, the Rhode Island Ophthalmological Society mounted an aggressive campaign to defeat a bill which would have allowed optometrists to prescribe and administer therapeutic drugs. The state's ophthalmologists were highly effective in convincing the legislature that such a move would endanger the public health. In response to efforts to expand the practice privileges of the physician's assistant, the Society again emphasized that PAs must function under the supervision of fully-licensed physicians. We also developed a revised format for the release of medical records which will be sent to all members later this year. As a result of this action, the sponsor of a bill which would have transferred ownership of records from the physician to the patient agreed to withdraw his proposal.

These political fights absorbed a considerable amount of time and energy. The laws and regulations covering non-physician providers in Rhode Island are extremely uneven as evidenced by the fact that nurse practitioners are not licensed. It has been suggested by some that the Society seek legislation which would authorize the Department of Health to license and regulate all health providers.

This year the Society introduced a package of five bills designed to alleviate the growing malpractice crisis. As four of these bills would have affected other kinds of liability from personal injury, we expected more support from the insurance industry and business leaders. While the legislative leadership was responsive to our problems, there was not enough support to secure passage of the reform package. The General Assembly did create a legislative study commission to address the malpractice crisis, thereby laying the groundwork for substantive reform during future sessions. The Rhode Island delegation to the AMA House of Delegates may introduce a resolution on the malpractice problem which should help considerably, if adopted. The AMA would be asked to provide documentation

justifying the need for special tort reform legislation and to draft model legislation capable of surviving the anticipated constitutional challenges.

On an upbeat note, we recently won a significant victory on the federal level with the defeat of several bills requiring the assignment of Medicare benefits. Although it is the hospital component of Medicare which faces bankruptcy, Congress anxiously is searching for ways to save the Medicare program. New proposals to regulate physician fees may well emerge next year. As a positive result of the discussion of this issue, however, we have developed valuable relationships with the Rhode Island Congressional delegation and a means of discussing other troublesome issues, such as the Federal Trade Commission and malpractice reform.

Another significant accomplishment was the publication and distribution of the *Guide to Physician Services*. Published in response to public requests for more information on physicians, it was a direct result of efforts by the late Doctor Melvin D. Hoffmann, the Society's immediate past president. Two weeks before his untimely death, he had the honor and pleasure of announcing the release of the directory at Governor Garrahy's press conference.

As for the future, we can expect malpractice cost to absorb our energies. With the help of the AMA and the new legislative commission, we should have by next year a viable package of legislation ready for introduction into the General Assembly. The Society can profit from the recent experiences of the ophthalmologists by mounting a personal campaign aimed at individual legislators, thus improving our chances of controlling our destiny.

As for Medicare, the harsh reality is that, as the result of technological advances and an aging population, the fiscal crunch will not be solved by "freezes," caps, or DRGs. Rather, the federal government must face some serious alternatives such as the rationing of medical care or spending less on defense. These are difficult choices. It is likely that Congress will seek the easiest way out politically by continuing to single out physician charges as the culprit, unless we protest in a unified voice.

By combining our efforts, the Society and the AMA have achieved a successful year with many accomplishments. As we are faced in the coming year with the pending struggles over malpractice reform and Medicare reimbursement, your continuing support and a strong commitment will be essential. ■

The Chronic Low Back Pain Syndrome: Identification and Management

Appropriate Treatment Should Lead to Better Services, Improved Health Status, and Reduction in Health Care Costs

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Chronic low back pain is one of the most prevalent, difficult, and expensive problems currently facing medicine. An estimated 50 million Americans are either partially or totally disabled by chronic pain at an annual cost of more than 40 billion dollars, including hospital and health care expenses, lost work productivity, sick pay, and compensation costs.¹⁻³ Moreover, these patients utilize a disproportionately large percentage of health care resources.⁴ A study performed by the Washington State Department of Labor indicated that while low back pain injuries of more than three months' duration accounted for only 4.5 per cent of work-related claims during a twelve-month period, they consumed 36.5 per cent of the total compensation budget for the same period.⁵

Even more significant is the cost of chronic pain in terms of human suffering. These patients typically experience a major disruption in their work, family, and social activities. Unfortunately, traditional medical and surgical interventions have been largely ineffective in treating chronic

pain.⁶⁻⁸ Only 30 to 40 per cent of chronic pain patients obtain significant long-term pain relief from surgical and medical techniques.⁹⁻¹¹ In addition, the multiple medical and surgical interventions that these patients receive often produce such iatrogenic complications as surgical scar tissue and medication side-effects which increase the severity and extent of the pain problem.^{1, 12, 13}

Many pain experts contend that traditional medical and surgical approaches have a poor success rate with chronic pain because they are aimed at only a part of the problem.^{14, 15} Chronic pain is seen as a different condition than acute pain. The evaluation and management of acute pain usually focuses exclusively on the underlying tissue pathology. However, the longer pain persists, the greater the contribution that psychological, social, and environmental factors are likely to have to the pain experience. Chronic pain, therefore, involves a complex interaction of psychological, social, and environmental variables as well as biological factors. This biopsychosocial model may be used to explain the unresponsiveness of chronic pain to repeated interventions whose singular focus is correcting the

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underlying physical pathology or blocking the "pain pathway." If pain complaints and disability persist, despite repeated medical and surgical interventions, it becomes imperative to shift to a more comprehensive biopsychosocial model of assessment. It must be emphasized that this conceptual shift does not involve distinguishing between functional and organic pain. It is impossible to establish a purely psychological etiology to pain, and a functional diagnosis is merely a diagnosis by exclusion that does not benefit the patient. Instead, the differential is whether the patient demonstrates signs of the chronic low back pain (CLBP) syndrome.

The patient suffering from this syndrome will present a constellation of interrelated problems, including persistent complaints of pain and such pain behaviors as moaning, facial grimacing, and limping; marked limitations in functional capabilities; depression and emotional distress; chemical dependency; marital and family discord; and vocational and financial difficulties. If a patient has multiple components of the CLBP syndrome, it is likely that repeated applications of acute-care strategies (ie, attempts to eliminate the nociceptive stimulus) will be of limited value and may possibly exacerbate the pain cycle. Consequently, when a patient experiences the chronic pain syndrome, it is necessary to shift the focus of treatment away from curative to rehabilitative.

The purpose of this paper is to identify and clarify the various components of the chronic low back pain syndrome and present an alternative approach to management of patients suffering from this difficult problem. The orientation and function of a multidisciplinary pain clinic is described, with specific reference to the Chronic Pain Treatment Program at The Miriam Hospital, Providence, Rhode Island.

Symptom Complex

When pain persists for a protracted period, the following symptoms, problems, or both often develop as components of the chronic low back pain syndrome:

Persistent complaints of pain and pain behaviors: Chronic pain is defined as pain that has persisted for a period of at least six months despite multiple medical and surgical interventions. It typically is experienced on a daily basis and often becomes incapacitating. Usually, there is no detectable pathology, or the degree of self-reported pain far exceeds discernible tissue damage. Patients with chronic pain usually display a wide variety of

readily-identifiable behaviors, including verbal complaints, grimacing, guarded movement, frequent position shifts, lying down, and avoidance of routine activities.

Fordyce has proposed a social-learning model to explain the persistence of such pain behaviors, at least in some patients, despite correction of the underlying pathophysiology.¹⁶ Under this model, there are two types of pain behaviors, operant and respondent. While respondent behaviors occur reflexively to antecedent stimuli arising from the site of the tissue damage, operant pain behaviors are controlled directly by environmental consequences. In a state of chronic pain, Fordyce contends, behaviors which were initially respondent in nature become operant in character through the process of learning. Pain behaviors may well be reinforced by sympathy and concern from others, the avoidance of unpleasant responsibilities, financial compensation, and, under certain conditions, medications.

Impaired functioning: Chronic pain patients frequently demonstrate marked impairment in functional capabilities characterized by an inability to engage in routine daily activities considered normal for their age and sex.¹⁶⁻¹⁸ Often pervasive, these impairments include limitations in social, recreational, and work activities, and restrictions in general mobility, range of motion, muscle strength, and ambulation.^{16, 19} To avoid movements or activities that may exacerbate discomfort, chronic pain patients increasingly restrict their functioning until pain and disability dominate their lives. They typically spend 33 per cent of their waking hours lying down for pain relief.²⁰

Emotional distress: A large proportion of chronic pain patients display significant levels of emotional distress characterized primarily by depression.^{18, 21-23} These patients, like those with other chronic conditions, face an uncertain prognosis and the possibility that they may never recover. At the same time, they often must abandon or dramatically reduce their work, social, and recreational activities which were previously central to their lives or served as primary sources of enjoyment. As a result, feelings of helplessness, hopelessness, and despair develop. Moreover, some chronic pain patients also exhibit anxiety, disordered thinking, agitation, poor impulse control, and social alienation.²¹ These patients may also reveal hostility, resentment, and a high level of suspicion, especially towards health care providers seen as responsible for their continued pain and suffering.

Chemical dependency: Chemical dependency is a frequent problem in patients suffering from chronic pain.^{18, 24} An estimated 50 to 65 per cent of these patients exhibit analgesic abuse, addiction, or habituation.^{13, 16} While pain relief medications may provide short-term pain relief, their utilization on a long-term basis affords neither sustained pain relief nor an improvement in overall functioning. Instead, the prolonged use of narcotics usually produces such adverse reactions as habituation, constipation, lethargy, and addiction.¹⁶ The provision of temporary pain relief through medication serves as a powerful enticement that leads the chronic pain patient to continue and gradually increase usage of these substances until psychological dependence, physical addiction, or both develop.

Marital discord: Chronic pain can have a devastating impact on the structure and functioning of the family system.^{18, 25} Family members, especially the spouse, often must function as supportive and nurturing caretakers, in addition to assuming roles and responsibilities previously held by the patient.²⁶ A spouse whose primary role had been a homemaker, as an example, may have to seek outside employment to replace lost income and support the family. Furthermore, it often is necessary to abandon joint activities (eg, sex, shared recreation, and so forth) that were previously reinforcing, thereby removing an important source of marital and family satisfaction. In addition to its devastating impact on the patient, chronic pain also poses significant demands on the spouse and others close to the patient. The adverse impact of chronic pain on marriage and families is perhaps best summarized by Shealy, who, in noting the 60 to 80 per cent divorce rate for chronic pain patients, concluded the "worse of 'for better or worse' does not include chronic pain."²⁷

Vocational difficulties: Disruption of vocational functioning is a nearly universal sequela of chronic pain. Unemployment among chronic pain patients is higher than 80 per cent.^{28, 29} The typical pain patient, upon arrival for evaluation at a multidisciplinary pain clinic, has been out of work for at least two years. Moreover, of those patients who maintain employment, most either work on a part-time basis or must take less physically demanding and often less satisfying and remunerative positions. As the vast majority of chronic pain patients are unable to maintain or return to their previous jobs, they require vocational retraining to become once again productive members of society.

Rehabilitation: An Alternate Goal

In the absence of progressive neurologic defects, it is best to shift the focus of treatment for chronic pain patients from a curative to a rehabilitative approach. These persons need to be helped to learn to live with their pain problem so that they may effectively cope with it and return to as normal and satisfying a life as possible. As in other chronic diseases where a cure is not possible, patients suffering from low back pain often derive the most benefits from an intervention designed to promote adaptation and increase functional capacity. Moreover, a multidisciplinary approach is required to address the broad array of problems that develop as a result of the condition.

In the past decade, there has been a proliferation of multidisciplinary pain clinics which primarily have relied on the application of behavior management strategies that emphasize the role and importance of environmental factors.^{16, 30} The primary purpose of the behavioral approach is not to alleviate pain, but to modify such maladaptive pain behaviors as excessive lying down, avoidance of activity, limping, excessive health care utilization, and other actions. This approach directly attempts to address the disability by combining behavior modification procedures with physical therapy, psychotherapy, and vocational counseling.

Several chronic pain treatment programs have reported their results with this approach. In a study which followed patients for periods ranging from five to 175 weeks after treatment, Fordyce et al found reports of significantly less pain, less interference with daily activities, reductions in the utilization of pain medications, and less time spent in bed as a result of pain.³¹ Anderson and his colleagues have reported that 25 of 34 patients (74 per cent) who completed an eight-week inpatient program were leading "normal" lives without medication when followed for between six months and seven years after discharge.³² In a long-term evaluation of the same program, Roberts and Reinhardt compared the treatment group to a group of 20 persons rejected for treatment and another group of 12 persons accepted for treatment, but who refused to participate. Of the comparison subjects, only one individual was leading a "normal" life without medication at long-term follow-up.³⁰ Cairns et al found that, at ten month follow-up, 75 per cent of their patients reported a significant decrease in pain and a corresponding increase in activity.³³ Fifty-eight per cent reported that they no longer required narcotic pain medications,

and 74 per cent sought no further medical advice. These findings suggest that approximately 70 per cent of the patients who enter a behaviorally-oriented multidisciplinary chronic pain treatment program show improvement at the end of treatment and at follow-up intervals.

The Miriam Hospital Chronic Pain Program

The outpatient-based chronic pain program at The Miriam Hospital follows a cognitive-behavioral model which is designed to retrain patients and their families in the management of the chronic pain syndrome. The goals of the program are to reduce the level of disability and frequency of pain behaviors; increase the physical capabilities and activities of patients to a level considered normal for their age, sex, and physical impairment; eliminate reliance on medications; and reduce utilization of medical care resources for purposes of pain relief.

Major components of the program include:

Behavior modification: These procedures are employed to modify maladaptive pain behavior and promote activity and more appropriate behavioral responses.

Physical therapy: A daily treatment program is designed to strengthen muscles which have been weakened by pain and disuse. Activity levels are gradually increased to the point where patients are performing tasks considered normal for their age, sex, and level of physical impairment.

Individual and marital counseling: Therapeutic services are provided to both patients and their spouses to address emotional distress and facilitate adaptation. The issue of depression is specifically addressed through individual psychotherapy and with pharmacotherapy where indicated. During marital or family therapy, patients and spouses are taught to identify pain behaviors and their responses to them. They are also trained to identify and reinforce appropriate or "well" behaviors. In addition, these sessions focus on other psychological and marital problems, including communication deficits and sexual difficulties which may be present.

Cognitive restructuring: As one of the most significant elements of the program, the process of cognitive restructuring involves helping patients to realize that, in order to return to a normal and satisfying way of life, they must take responsibility for these changes. This is accomplished by directly challenging such irrational beliefs as "I should have no pain" and "Once you eliminate my pain, all of the other problems in my life will automatically be resolved." Patients who expect

total pain relief or expect health care professionals to eliminate their pain will engage in a relentless search for the "magic treatment." If they recognize that total relief may not be possible and assume the responsibility for controlling the influence of pain on their lives, these patients will abandon the search for an elusive cure and will start the process of adaptation. The program helps patients realize how pain behavior has become a way of life. Patients learn to "control" pain by reducing its influence on their behavior and the lives of others around them.

Vocational counseling: The ultimate goal of treatment is to assist patients in returning to work or some other functional activity as well as in resuming domestic responsibilities. This often requires vocational counseling and, where indicated, vocational retraining.

Evaluation and Treatment Procedure

During a comprehensive evaluation process, patients are carefully screened to determine their appropriateness for the pain treatment program. Because not all chronic pain patients are suitable candidates for a behaviorally-oriented program, this evaluation is essential. Treatment requirements of individual patients vary widely according to the relative contribution of biological, psychological, social, and environmental factors in each case. Prior to acceptance, a set of inclusion and exclusion criteria must be met. Patients with minimal tissue damage or correctable pathology who are functionally impaired and exhibit maladaptive pain behaviors are viewed as the most appropriate candidates for rehabilitation.

The program begins with a formal evaluation week at which time a treatment agreement is reached which specifies the elements of treatment and goals for that particular patient. Following this phase, the patient begins six weeks of active treatment that involves physical therapy three times a week, outpatient counseling, marital and family therapy, and other individual treatment sessions considered necessary for that particular patient such as anxiety management training, social skills training, and so forth. At the end of the six-week period, the patient will have achieved the agreed-upon exercise and activity goals and will remain at that goal level for the final week of treatment. During the final week, patients may challenge any member of the treatment team to complete the exercise program with them, and also view videotapes of their exercise performances from pre- and post-treatment periods.

After completion of the eight-week treatment program, patients and their spouses participate in the follow-up program. Approximately 24 weeks in duration, it is designed to assist patients in maintaining the gains made over the course of treatment. The specific elements of the follow-up program depend upon individual problems and strengths. These elements are designed during the discharge conference, which takes place at the completion of the eight-week period. Follow-up consists of visits to physical therapy, which gradually taper in frequency over the six-month period. In addition, the patient is also seen on a gradually reduced schedule of individual sessions, marital therapy, or both. The follow-up component allows for careful monitoring of the rehabilitation process. If the symptoms or disability recur, both physical therapy and individual counseling sessions are arranged. Counseling or emotional support is provided during this period. In the event of a loss in physical functioning, patients are assisted in constructing exercise charts and graphs to help them work back to their prior level of physical functioning.

Conclusion

This treatment approach obviously is not appropriate for all patients, especially those with

multiple and progressive neurologic defects. However, there is a significant proportion of patients suffering from persistent low back pain despite multiple treatment interventions for whom a cure no longer is a reasonable expectation. The program at The Miriam Hospital is designed to assist patients suffering from the chronic pain syndrome in increasing their functional capacity and adjustment. It is our belief that this alternate approach benefits not only the patient, but also the health care system. The early identification of patients suffering from the chronic low back pain syndrome and a shift in the focus of management from a curative to rehabilitative stance should lead to provision of better health care services, improvements in health status, and, ultimately, to lower health care costs for treating this difficult condition.

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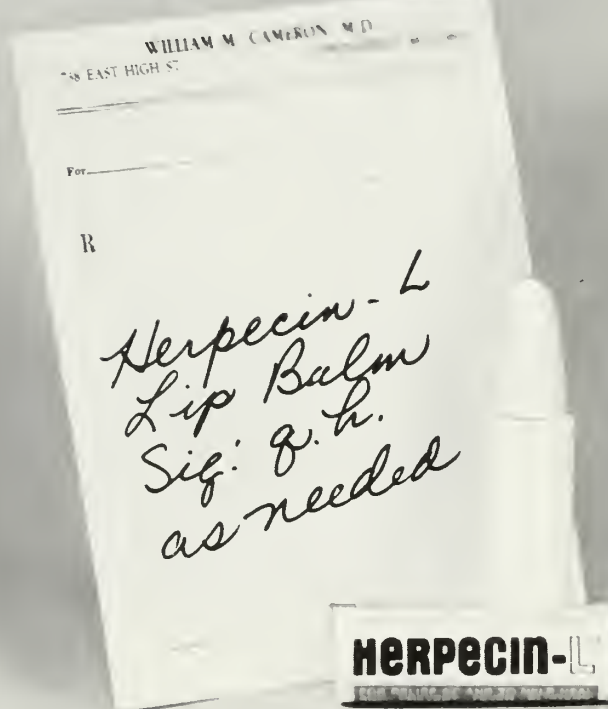
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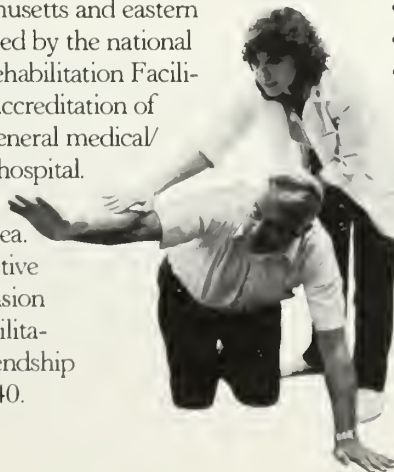


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- 2) All papers must be double-spaced and should not exceed 10,000 words.
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The Use of Electroretinograms (ERG) in Diagnosing Retinitis Pigmentosa and Related Visual Disorders

Test Is Dependable and Gives Valuable Information within the Limits of Its Capability

Michael Somers, BA
Arthur I. Geltzer, MD

Retinitis pigmentosa and other related retinal diseases affect one in 4,000 persons in the United States.¹ A history of change in either night or peripheral vision may be the only presenting symptom. A family history of night vision deficit or blindness of unknown cause may be elicited. The ophthalmological examination may show bony spicule pigmentary changes, arteriolar narrowing, disc pallor, or no clinical signs. The diagnosis of retinitis pigmentosa and other degenerative conditions rests primarily with the results of the electroretinogram (ERG).

This test, which represents the summed mass electrical discharge of rods and cones, is a sensitive indicator of global disease involving the retina. Indeed, it has been compared to the electrocardiogram, which is used to measure deficiencies in the heart and its conducting system. In evaluating the ERG, an estimation of the general development of the wave form is made. There is a transition from the *a* wave in the photopic light adapted state to a predominant *b* wave in the scotopic dark adapted state.

The absence of the *b* wave indicates the pres-

ence of severe retinal disease. With the proper clinical setting, a diagnosis of retinitis pigmentosa or rod degeneration can be made. If the *b* wave is present, but of diminished amplitude, early degeneration can be diagnosed. However, the most subtle electrophysical observation of a diseased retinal state is an increase in the latency or implicit time.² This time period refers to the time necessary to generate the *b* wave (Fig 1).

Numerous computerized and sophisticated ERG units, at a cost ranging between \$40,000 and \$80,000 each, have been introduced. They have provided elaborate data about the electrophysical activity of the retina and have facilitated research into the cause and nature of such retinal diseases as retinitis pigmentosa.³ This study was performed to determine if a screening ERG unit, purchased by the Rhode Island Hospital Guild for \$5,000, could provide useful information in the clinical setting for diagnosing retinitis pigmentosa and other retinal degenerative states.

Methodology

The subjects, nine males and 14 females, ranged in ages from 9 to 80 years. The criteria for obtaining an ERG included positive clinical symptoms; positive fundusoscopic findings; positive family history; and in two cases, the prognosis of a vitrectomy. A Grass PS 22 photostimulator was used with the Sonometrics ERG plug-in module to an Ocuscan 400® unit. The oscilloscope frequency was set at 60 cycles/second. A linear amplifier was used with the low and high band pass frequency settings at 1 and 300 Hz respectively. As no Ganzfeld diffuser was utilized, a photostimulator was placed 18 inches from the eye tested.

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Table 1. — Electroretinograms

Number	Patient	b-Wave Amplitude	Flicker Fusion	Implicit Time	Diagnosis
1	AG	220	X	ND	Siderosis
2	MB	260	X	ND	Normal
3	WB	300	X	37.2	Normal
4	KB	440	X	ND	Normal
5	AB	0	red	*	Retinitis Pigmentosa
6	HB	280	X	ND	Normal
7	AB	180	X	37.1	Vitrectomy
8	MB	0	red	*	Oguchi's
9	ME	410	X	39.8	Normal
					Advanced
10	EF	0	red	*	Retinitis Pigmentosa
11	AH	0	ND	ND	Vitrectomy — Early
12	RH	190	X	ND	Retinitis Pigmentosa
13	HK	290	X	39.2	Vitelliform
14	KL	200	X	ND	Gyrate Atrophy
15	EK	420	X	ND	Normal
16	EM	0	red	ND	Usher's
17	LM	0	red	ND	Usher's
18	RP	60	ND	ND	Stargardt's
19	BR	340	X	ND	Normal
20	RS	410	X	ND	Normal
21	RT	0	red	*	Vitelliform — Early
22	BW	290	X	ND	Retinitis Pigmentosa
23	JW	210	X	37.1	Retinitis Pigmentosa

Key

b wave amplitude measured in microvolts

flicker fusion graded as present (X), absent (-), or reduced (red)

b wave implicit time measured in milliseconds

* — unable to calculate time since no wave form present (infinite time)

ND — not determined (see discussion)

The protocol followed in the study was a slight modification of the first protocol outlined by Ronald Carr in *Visual Electrodiagnostic Testing*⁴ (p. 19) and included the following sequence:

Light adapted ERG: High intensity single flashes set at S₁, S₈, and S₁₆, followed by a short burst of high intensity flicker at a rate of 30/second (referred to as "flicker fusion").

Dark adapted ERG: After 10 minutes of total darkness, a blue filter was used with high intensity flashes set at S₁, S₈, and S₁₆.

The following data are found in Table 1: b wave amplitude, flicker fusion response, and b wave latency. Figure 1 shows how these values were calculated. The b wave amplitude is measured in microvolts, b wave latency in milliseconds (msec), and flicker fusion response was graded as present (x), absent (-), or reduced (red).

Results

The results are summarized in Table 1. The normal values for our unit were determined to be: b wave amplitude — 350 microvolts (standard deviation of 50 microvolts with a normal of 250-450 microvolts); b-wave latency of 42.5 milliseconds (standard deviation of 3.5 milliseconds with a normal of 35 to 50 milliseconds); and flicker fusion of 30/second normal for cone response. The rod will not normally respond to repeated flashes of light.

Case Reports

Two case reports are presented as representative examples.

Case 1: C.M. was a 23-year-old white female with a history of three years' duration of difficulty seeing in the dark, and deafness since birth. Her vision was 20/30 OU, and her color vision was

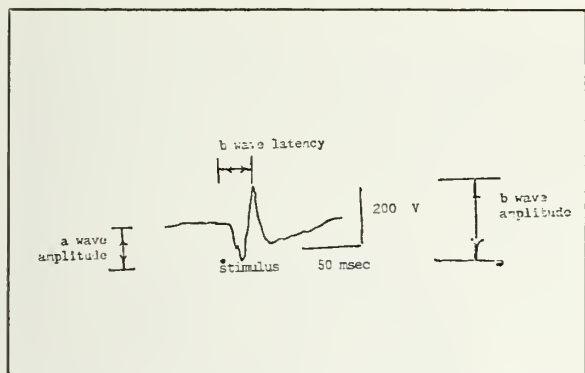
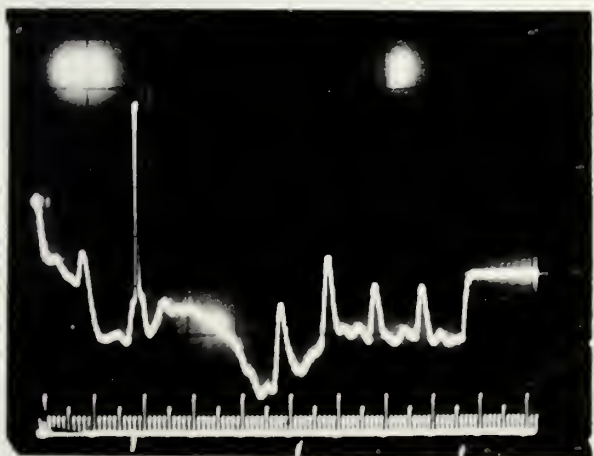
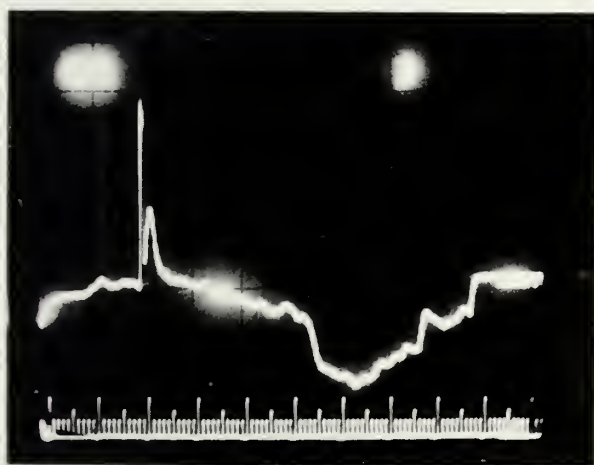


Fig 1. Typical wave form dark adapted patient showing the stimulus, the initial negative *a* wave. The subsequent positive *b* wave demonstrates the designation of the latency in milliseconds as the time from the stimulus to the peak of the *b* wave and demonstrates the designation of the amplitude of the *b* wave as a measurement from the lowest point of the *a* wave to the highest point of the *b* wave in volts on the oscilloscope. The real time on the oscilloscope is calculated from the sweeps of the oscilloscope and the amplitude is calculated from a standardized impulse.



normal. Funduscopy examination revealed pigmentary changes in the periphery with occasional vessel narrowing. Her ERG is presented in Fig 2. The *b* wave response is flat. The dark adapted state demonstrated severe rod disease. The flicker fusion is present and of normal amplitude, showing normal cone response. Goldmann perimetry revealed constriction of her nasal fields OU (Fig 3).

Case 2: N.P. was a 13-year-old white male referred because of recent loss of vision in the left eye. He had a mild amblyopia in his right eye since birth. There was no family history of retinal degeneration. A paternal grandfather reportedly had glaucoma leading to blindness at age 60.

The physical examination revealed a corrected vision of 20/40 in the right eye and 20/70 in the left eye. The anterior segments were normal, without evidence of cataract or inflammation. Intraocular pressures were normal. An initial examination showed chronic edema of the optic nerve and abnormal vessels in the peripapillary region (Fig 4). Six months later, the optic nerves became pale with attenuation of the vessels. There were no pigmentary changes suggestive of retinal degeneration.

An ERG was performed with the Ocuscan 400® and showed a flat response to scotopic and photopic stimuli. The cone response, however, was intact, with normal flicker fusion (Fig 5). From the screening studies, a diagnosis of retinitis pigmentosa was made. The studies were repeated at the Boston (Massachusetts) Children's Hospital confirming the diagnosis of retinal degeneration (Fig 6 courtesy of Anne Fulton, MD).

Discussion

We concluded from this study that the Sonometrics module is a reasonable instrument in a community setting for diagnosing retinitis pigmentosa; determining if a reduced visual acuity is due to an organic cause; estimating potential vision prior to cataract or vitreous surgery; or determining if a retained metallic foreign body is

Fig 2. The ERG response for a patient with a fundus abnormality, a positive history of nerve deafness, and difficulty in night vision. The upper picture shows the flat *b* wave response in the dark adapted state demonstrating essentially no rod response to such a stimulus. The lower picture represents the flicker fusion response at 20 cycles per second, a normal response in amplitude and frequency which suggests that while there is severe rod disease, the cones are not affected.

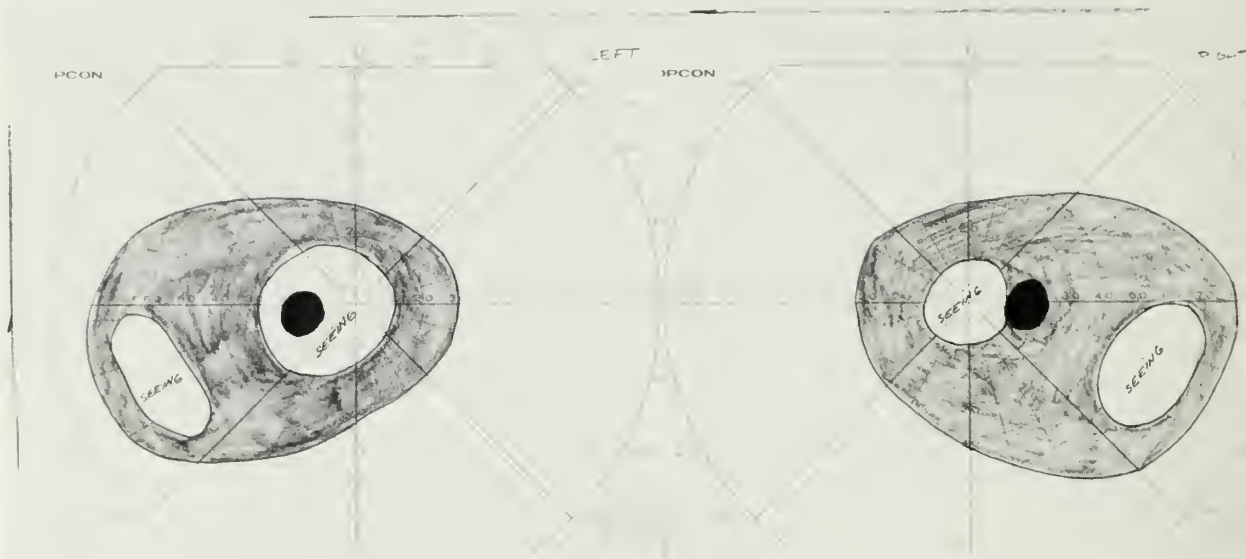


Fig 3. Case 1: Visual fields show severe peripheral constriction to I, II, and IV test objects on a Goldman field test.

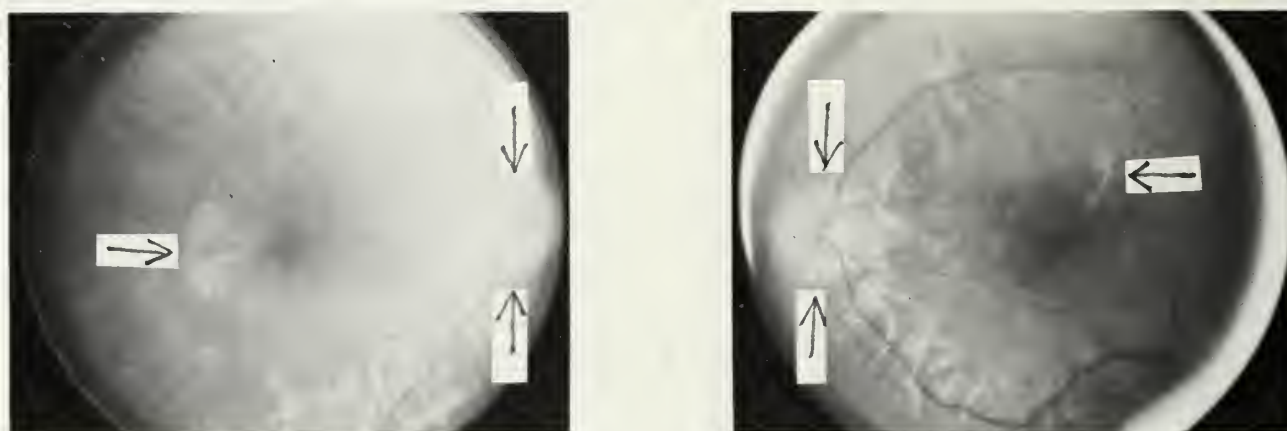


Fig 4. Case 2: Arrows show the edema of the optic nerve and peripapillary edema of the macula.

causing retinal damage.

Retinitis pigmentosa is a progressive destructive disease that causes a marked decrease in the amplitude of the *b* wave. Under scotopic conditions, this decrease represents destruction of photoreceptors and bipolar cells. The destructive nature of retinitis pigmentosa usually involves the rods initially with subsequent damage to the cones. The "flicker fusion" response, by bleaching out the rhodopsin pigment through repeated stimulation, allows a selective evaluation of cone function. This study confirmed that patients with a longstanding history of retinitis pigmentosa have neither cones nor rods functioning on ERG examination, while those in the early stages of the disease showed a normal flicker fusion response.

Of the eleven patients demonstrating *b* wave amplitudes below 250 microvolts (lower than normal limit), ten were confirmed by further testing at Boston Children's Hospital with sophisticated computerized equipment. The patients who presented a diagnostic problem were within a range of 180 to 250 microvolts. Perhaps with these patients, the Sonometrics unit is not sensitive enough for an unequivocal diagnosis, thus requiring a referral for additional testing at other centers. As a preliminary screening test for retinitis pigmentosa, however, the Sonometrics unit is quite appropriate.

Of note is the fact that only a blue filter was utilized under scotopic conditions. There appears to be no additional benefit in recording the scotopic response using red and white filters, as is

done elsewhere.

As stated above, the ERG examination permits an estimation of the general development of the wave form. While the *b* wave amplitude is of paramount importance, the most subtle electrophysiological change of a diseased retinal state is an increase in the latency or implicit time. The sample reported in this study is not large enough to determine if the latency or implicit time can be accurately measured with the screening test described above. The latency measurements reported in this study, however, were felt to be reproducible within the sample group presented.

Also significant is the fact that we did not use a Ganzfield diffuser. According to Carr and Siegel, an open flash without a Ganzfield diffuser produces an intense image on the retina and a substantial amount of scattered light throughout the interior of the eye.^{4 (p. 25)} An ERG produced by the weaker portions of the scattered light would

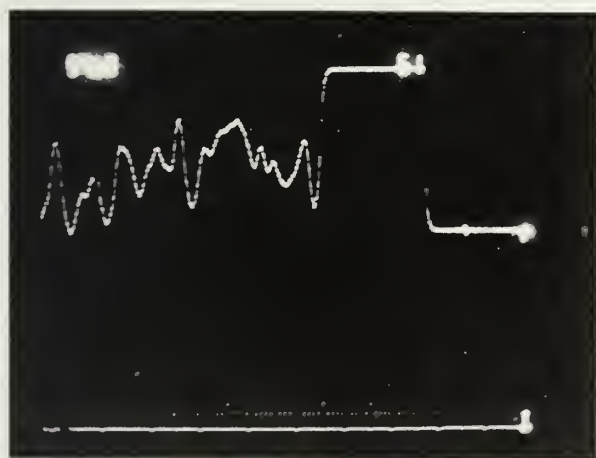
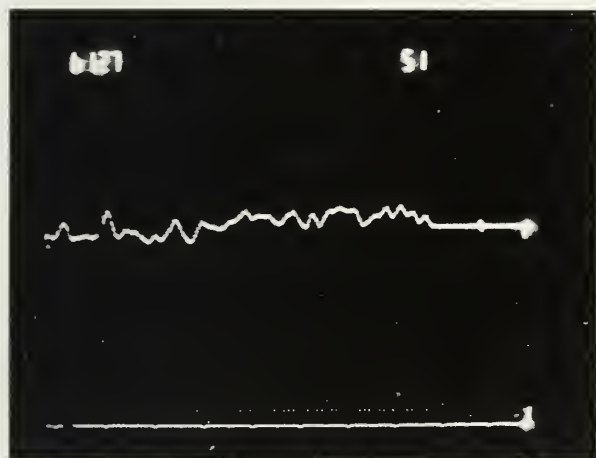


Fig 5. Case 2: Studies with the Sonometrics scanning unit showing the flat response in the upper picture to a scotopic *b* wave and a normal cone response in the lower picture to flicker fusion. This suggests intact cones with a dystrophy of the rods.

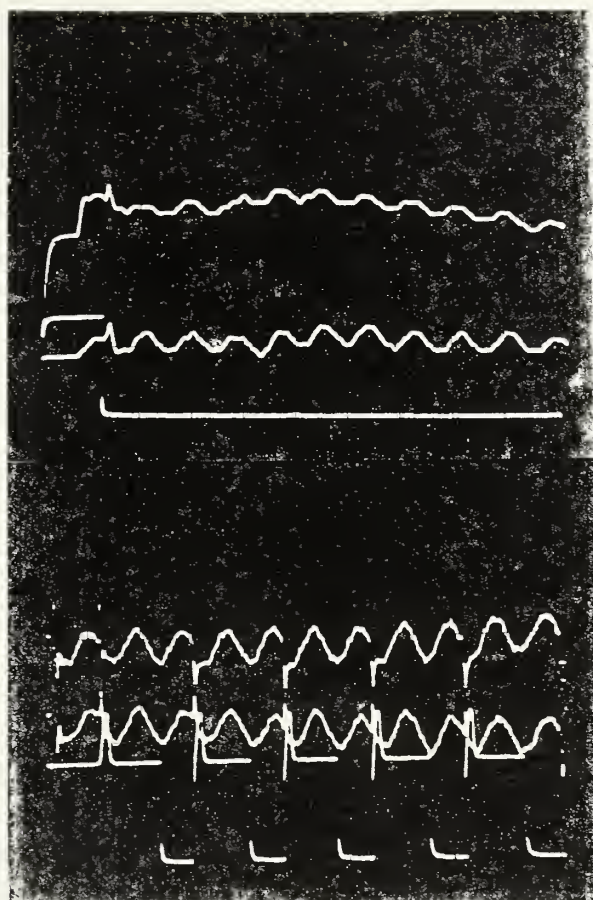


Fig 6. Case 2: Confirmation of the flat response of the rods to scotopic stimuli and normal flicker fusion showing normal cone response as confirmed on sophisticated electroretinographic studies at Children's Hospital, Boston (courtesy of Anne Fulton, MD).

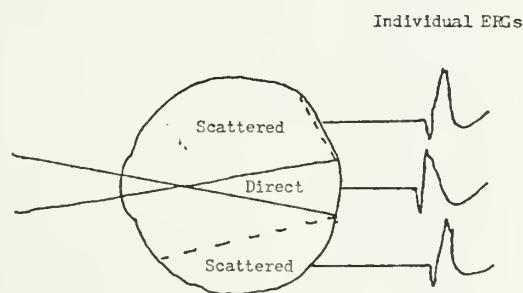


Fig 7. Demonstrates the difficulty of doing an ERG with a focal source of illumination where there is direct light giving one wave form and scattered light giving another wave form. The use of a hemisphere illumination would eliminate this problem and permit a more accurate measurement of the latency time, the period from the stimulus to the peak of the *b* wave.

have longer latencies and smaller amplitudes than one generated by the direct-image flash (Fig 7). Carr and Siegel conclude that, since the recorded ERG is a summation of all electrical activity, wave form latency estimates cannot be accurately determined. The Ganzfield diffuser may prove to be necessary for a specific diagnosis of retinitis pigmentosa. Our study suggests, but does not prove, that a diagnostic study can be performed with a simple flash source rather than a diffuser.

The next step in ascertaining the necessity of using a Ganzfield diffuser during the examination would be to determine whether it is possible to document a lengthening of the implicit time in a group of patients with recent onset of retinitis pigmentosa. Moreover, if the progression of this disease can be followed by documenting a gradual lengthening of the implicit time with eventual changes in the amplitude and flicker fusion responses, the usefulness of the Sonometrics unit would be readily demonstrated.

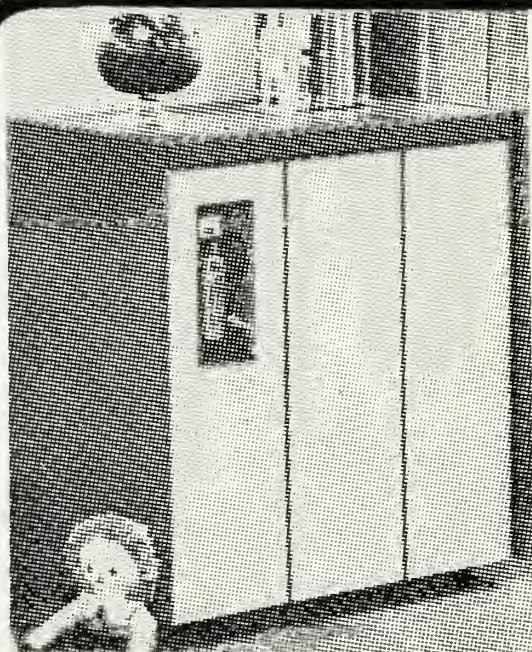
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Summary

Twenty-three patients were evaluated with a screening electroretinogram to determine the presence of retinitis pigmentosa; reduced visual acuity on an organic basis; a potential for improved vision prior to cataract or vitreous surgery; or retinal damage secondary to a metallic foreign body. An accurate diagnosis was made in each case and confirmed by more sophisticated testing in several instances. It would appear that this test is dependable and provides valuable information within the limitations of its degree of sophistication.

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Multiple Abnormalities in a Preterm Infant with Growth Retardation

Richard M. Cowett, MD
Don B. Singer, MD

Clinical Findings

The patient was female, the first-born child of a 33-year-old mother who took Clomid® to facilitate pregnancy, but stopped the drug after conception. The uterus enlarged more slowly than normal throughout pregnancy. The infant weighed 730 grams at 36 weeks gestation as indicated by dates, but was 26 weeks as determined by ultrasound. Fetal movement was poor during the latter part of pregnancy. Cesarean section was performed because the fetal monitor disclosed late decelerations of the heart rate. The infant had Apgar scores of 1 at 1 minute, 1 at 5 minutes, and 3 at 7 minutes.

On physical examination, the baby had a large cranium with a small face, micrognathia, flat nasal bridge, flat anterior fontanel with open sutures and low set ears. Purpura was present on the chest, back, and legs. A systolic murmur, Grade III/VI was heard with a gallop rhythm and hyperdynamic precordium. Pulses seemed normal in all four extremities. The abdomen was soft, the liver was palpated 1-2 cm below the costal margin, and the spleen was not enlarged. Genitalia were those of a normal female. The second

and fifth fingers overlapped the third and fourth fingers.

Initial radiographs disclosed cardiomegaly and opacification of the left hemithorax with eventration of the diaphragm and the liver protruding into the chest. There was abundant gas in the bowel.

The initial laboratory data included a white blood count of 4900 per mm, with 25 per cent segmented neutrophils, 14 per cent band forms, 41 per cent lymphocytes, 13 per cent monocytes, and 7 per cent eosinophils. The hemoglobin was 12.3 gm/dL and the hematocrit 38.4 vol per cent. There were 464 nucleated red blood cells per 100 white blood cells. The platelet count was only 5000 per mm. The blood groups of both mother and infant were O, Rh positive, and a Coombs test was negative. Glucose, electrolytes, and calcium initially showed normal values, but the glucose dropped to 24 mg/dL at 6 hours of age.

A suction catheter could not be passed into the stomach. The baby was intubated and given oxygen, 100 per cent FiO₂ with high ventilatory pressures and rates. By the second day of life, digoxin was administered because of congestive heart failure of uncertain etiology. A patent ductus arteriosus was suspected. On the third day of life, sepsis workup was performed, but all of the cultures were subsequently negative. Antibiotics were continued. Despite maximum ventilatory assistance, the clinical condition continued to deteriorate, and the infant died on the fifth day. Just prior to death, the anterior fontanel became full and intraventricular hemorrhage was suspected.

Discussion

Richard M. Cowett, MD: The discussion today concerns a baby with intrauterine growth re-

This is one of a series of clinicopathological conferences conducted under the auspices of the Department of Pathology, Brown University Program in Medicine.

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tardation (IUGR). Fetuses with IUGR are at risk for being stillborn as well as having a number of neonatal morbidities. A significant portion of the progress made in perinatology during the last decade has been due to prenatal and postnatal diagnosis and the appropriate management of the IUGR infant.

Let us first consider the etiological factors in intrauterine growth retardation. These may be based on environmental, maternal, placental, and fetal factors (Table 1). Environmental factors are the critical determinants of the growth potential of a fetus. Average birth weights vary widely

Table 1. — Causes of Intrauterine Growth Retardation

Environmental factors:
Ethnic
Race
Socioeconomic status
Geographic location
Malnutrition
Maternal factors:
Small stature
Primiparity
Grand multiparity
Low prepregnancy weight
Young maternal age
Smoking
Alcohol and other drugs
Cardiac disease
Placental factors:
Diabetes
Aberrant cord insertion
Hemangiomas
Vascular thromboses
Single umbilical artery
Abruptio placenta
Fetal factors:
Congenital abnormalities
Chromosomal abnormalities
Infections
Metabolic problems
Multiple pregnancy

among different populations, and ethnic origin and racial background may influence size separately or may be linked to socio-economic status, geographic location, and the presence or absence of malnutrition. These factors may be additive depending on the population studied. If socio-economic status results in malnutrition, as an example, medical attention may not have been sought during pregnancy. Malnutrition is remedial, since caloric supplementation to the pregnant woman can alleviate some of the effects of prior deprivation. Treatment is most beneficial during the third trimester when the diagnosis is

most easily made and when good nutrition is most critical. As there is a geometric rate of growth between the 28th and 40th week of pregnancy, deviations from the normal would be most apparent during this period. In the case of this baby, because fundal growth was poor throughout pregnancy, environmental factors can probably be ruled out.

Many maternal factors influence the growth of a fetus. A young woman of small stature and low prepregnancy weight has an increased chance of delivering a small infant. First-born infants and those born after multiple pregnancies also tend to be small. The woman who smokes and drinks may also produce a small infant. However, if she stops smoking before the third trimester, the development of the IUGR infant may be ameliorated. In preeclampsia, fetal growth decreases about four weeks before the clinical appearance of maternal hypertension, reflecting subclinical changes in uteroplacental hemodynamics. Long-standing diabetes mellitus

Table 2. — Neonatal Morbidities in IUGR Infants

Perinatal asphyxia
Meconium aspiration and respiratory distress
Persistent fetal circulation
Hypoglycemia
Hypocalcemia
Polycythemia and hyperviscosity
Acute tubular necrosis
Necrotizing enterocolitis
Post-asphyxial encephalopathy

with vascular disease may result in infants who are growth retarded. Information regarding the mother in this case does not include any of these conditions.

Decreased transfer of substrate through the placenta is another major mechanism in IUGR. The inadequate gas exchange resulting from this mechanism can produce perinatal asphyxia. If glycogen stores are inadequate, the IUGR fetus responds especially poorly to hypoxic perinatal events. Perinatal asphyxia prompted the emergency operative delivery of this infant. It is likely that purpura on the back and the legs, a low white count, and low platelet count are directly related to perinatal asphyxia. Disseminated intravascular coagulation must also be considered as being present.

Respiratory assistance was required immediately after birth with high ventilatory pressures and 100 per cent oxygen. While an infant at 36 weeks by date should not have respiratory

distress syndrome secondary to surfactant deficiency, it is possible that phosphatidyl glycerol would not be present. The infant may not be "asphyxia resistant," and surfactant production may not have functioned under these circumstances. Another result of asphyxia is the stormy terminal course culminating in a suddenly full fontanel, probably a sign of intraventricular hemorrhage.

Early diagnosis of IUGR is necessary if fetal demise, asphyxia, or both at birth are to be avoided. The ultrasonic and electronic diagnostic tests used to diagnose IUGR may also detect a compromised fetus. Cesarean section and immediate neonatal resuscitation can decrease the adverse effects of asphyxia. Other problems may also occur in the IUGR infant. Among these are meconium aspiration and respiratory difficulty, persistent fetal circulation, hypoglycemia, hypocalcemia, polycythemia, acute renal tubular necrosis, necrotizing enterocolitis, and post-asphyxial encephalopathy (Table 2).

What was the cause of IUGR in this patient? Environmental and maternal causes would not produce IUGR prior to the third trimester and are not present here. Fetal infections, especially those in the TORCH group (Toxoplasmosis, Rubella, Cytomegalovirus [CMV], and Herpes) may be a factor. CMV can produce intrauterine growth retardation without other stigmata. Since most women either have a natural immunity or have been immunized prior to pregnancy, rubella now is considered rare. Congenital infection can be dismissed as a cause, since this infant had no supporting physical findings. The mother noted poor fetal movement during pregnancy, and the infant was only 26 weeks by size at delivery during the 36th week of gestation. This suggests that the infant stopped growing normally at or before the 26th week of gestation.

Among other possible causes are congenital anomalies. It seems unlikely that a baby who had only a patent ductus arteriosus (PDA) would require digoxin for cardiac failure at two days. PDA is more commonly seen in infants who are born at an earlier stage of gestational development than was this infant. Such premature infants usually have persistent high pulmonary vascular resistance which prevents a left to right shunt. PDA, if it were present, must have been part of a complex congenital heart malformation. Another anomaly was detected when a suction catheter could not be passed into the stomach. Since abundant gas was noted in the bowel on an abdominal x-ray film shortly after birth, upper esophageal atresia

with a tracheoesophageal fistula to the lower esophageal segment must have been present. This abnormality is more likely to be associated with polyhydramnios than with IUGR.

Chromosomal abnormalities remain a real possibility and must include consideration of trisomy 13, 18, or 21. The fact that the baby did not have a midline defect would decrease the possibility of trisomy 13. Because trisomy 21, or Down's Syndrome, was not obvious on physical examination, trisomy 18 seems most likely. This condition, first recognized in 1960 by Edwards, Patau, and Smith in three separate reports, is a common multiple malformation syndrome with an incidence rate of approximately 0.3/1,000 newborns. There appears to be a 3:1 preponderance of females to males. More than 130 different abnormalities have been noted in infants with this syndrome, including feeble fetal activity, severe growth deficiency, mental deficiency, prominent occiput, narrow bifrontal diameter, low set malformed auricles, small oral opening, micrognathia, clenched hands, and the tendency for the overlapping of the index finger over the third and the fifth finger over the fourth. Fingernails and toenails, especially of the fifth finger and toe, are hypoplastic. These babies have a short sternum and small nipples. Inguinal or umbilical hernias have been noted as well as the presence of a small pelvis. Cardiac defects may be of any type, but ventricular septal defect and patent ductus arteriosus are most common, found in 50 per cent of these patients.

Finally, Clomid®, if given to promote conception, was not a factor in this case, although there has been at least one case report of a tracheoesophageal fistula occurring after administration of this drug. In our case, however, Clomid® was administered prior to the pregnancy. I assume that it was stopped according to the standard administration protocols at the time the pregnancy was diagnosed. It would not have affected fetal development of the trachea and esophagus.

In view of the poor fetal movement, the retarded fundal growth early in the pregnancy, and the likely possibility that this infant stopped growing during the second trimester, I believe we are faced with a major chromosomal abnormality. Trisomy 18 is the most likely diagnosis. Many of the problems that were present were due to perinatal asphyxia superimposed upon the chromosomal abnormality.

Doctor Cowett's Diagnosis

Intrauterine growth retardation, probably secondary to trisomy 18

Perinatal asphyxia with intracranial hemorrhage

Tracheoesophageal fistula

Complex congenital heart disease, probably ventricular septal defect, and patent ductus arteriosus

Thrombocytopenia, probably secondary to asphyxia

Pathological Findings

Don B. Singer, MD: The autopsy disclosed several malformations with the most profound evident in the cardiovascular system. A double outlet



Fig 1. Opened left ventricle exposing high muscular ventricular septal defect (arrow). The aorta and pulmonary artery were transposed and both arose from the right ventricle (not shown).

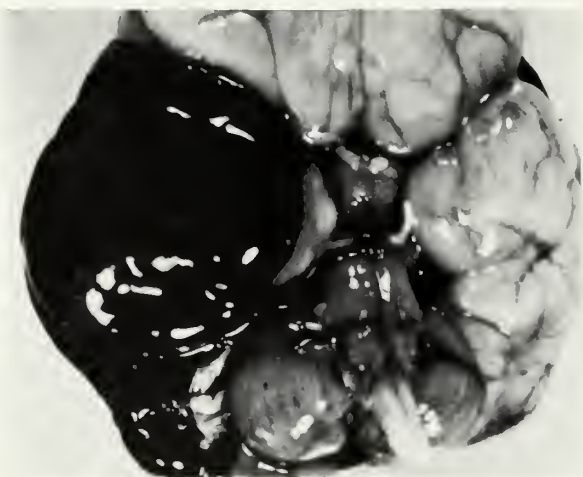


Fig 2. Right cerebral hemisphere with extensive subarachnoid hemorrhage. Parenchymal hemorrhage was minimal.

right ventricle with pulmonary infundibular chamber arising from the main chamber and a high membranous and muscular septal defect in the ventricular septum were observed (Fig 1). While transposition of the great arteries was another feature, this is not a significant malformation with regard to pathophysiology, since both vessels arose from the same chamber. The ductus arteriosus was patent. In the urogenital tract, focal dysplasia of the kidneys was noted, and the kidneys were small but otherwise normal.

A tracheoesophageal fistula was present with atresia of the proximal end of the esophagus, the lower end arising from the trachea in the most common form of this malformation. The fundus of the stomach had become necrotic and had perforated, probably a stress reaction from the increased intracranial pressure. This was due to a massive subarachnoid hemorrhage in the right parietal and temporal region and in the substance of the cerebrum (Fig 2). No intraventricular hemorrhage was noted. The combination of hypoxia and the extremely low platelet count led to the bleeding.

Although olfactory nerves may be absent in some cases of trisomy 18, they were present in this case. The dysmorphic features noted clinically were again identified at autopsy, and chromosomal analysis proved that trisomy 18 was the basis for the growth retardation and other problems (Fig 3). In a recent review of pathologic features of chromosomal abnormality, Opitz and Gilbert have shown that all of the anomalies noted here, including tracheoesophageal fistula, are fairly common in trisomy 18.¹ From the pathological findings, the most unusual and still unexplained lesion is the subarachnoid hemorrhage. Platelet counts of 5000 per mm are rare in

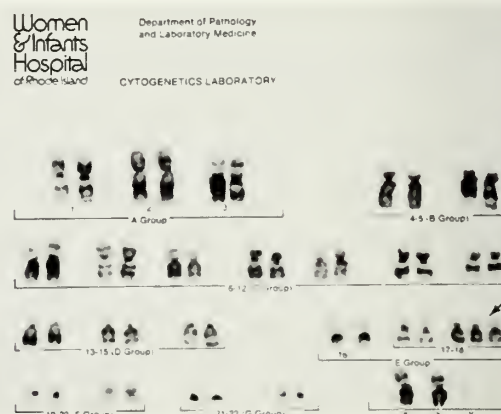


Fig 3. Banded karyotype of lymphocytes from the peripheral blood; extra chromosome 18 indicated by arrow.

neonates unless the mother has autoimmune thrombocytopenia and maternal antiplatelet antibodies have crossed the placenta. We did not test for anti-platelet antibodies in this infant.

Anatomic diagnosis

Trisomy 18 with multiple anomalies:

- Double outlet right ventricle
- Transposed great arteries
- Ventricular septal defect
- Esophageal atresia
- Tracheoesophageal fistula
- Bilateral anterior diaphragmatic hernias
- Dysmorphic facies
- Simian palmar creases and abnormally clenched fists
- Focal cystic adenomatoid changes in lungs
- Focal dysplasia in kidneys
- Pancreatic islet hyperplasia
- Subarachnoid and intracerebral hemorrhage

Thrombocytopenia

Fundal perforation of stomach due to stress ulcer

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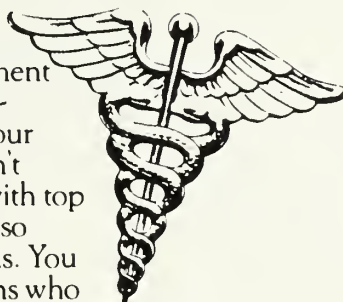
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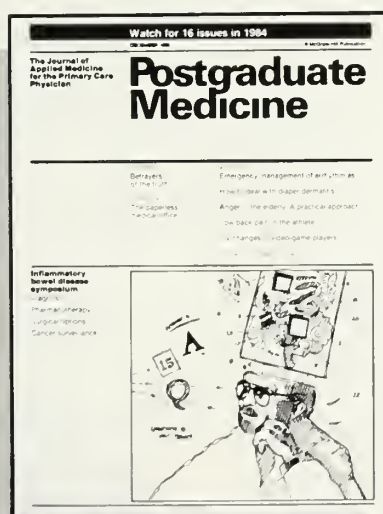
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A Case of Amenorrhea and Decreased Vision

Apparently Unrelated Symptoms May Be Manifestations of the Same Disease Process

Fred Brosco, BA
Tom J. Wachtel, MD

A case of benign intracranial hypertension and amenorrhea is reported because the apparently unrelated symptoms of menstrual irregularities and blurred vision may be manifestations of the same disease process.

Case Report

The patient, a 22-year-old obese white female, was in her usual state of health until five months prior to admission when she presented to her gynecologist with a complaint of three successive months without a menstrual period.

The history, general physical examination and routine screening tests, including thyroid function tests and pelvic examination, were normal. She denied the presence of galactorrhea. A pregnancy test was negative, and prolactin levels were normal. A Provera® (medroxyprogesterone acetate) trial of 10 mg daily for five days elicited menstrual bleeding. Lo/Ovral® (norgestrel 0.3 mg and ethinyl estradiol 0.03 mg) was prescribed with subsequent induction of regular menses.

Five weeks prior to admission, she noted the onset of throbbing fronto-occipital headaches, blurred vision, nausea, and vomiting, which be-

came progressively worse. She presented to her ophthalmologist, who found bilateral papilledema and enlarged blind spots in both eyes. She denied the presence of diplopia, dizziness, seizures, weakness, paraesthesias, or any history of head trauma.

The physical examination at that time revealed a morbidly obese woman with a blood pressure of 120/75, pulse of 72, and a temperature of 98.6°F (37.7°C). A fundusoscopic examination was significant for bilateral papilledema with proteinaceous deposits noted around the area of the optic disks. The neck was supple. The heart, lung, abdominal, and neurological examinations were within normal limits. The patient was alert and oriented.

Discussion

The evaluation of secondary amenorrhea should begin with a pregnancy test. If the result is negative, a serum prolactin level should be ordered and a progesterone withdrawal test performed, eg, Provera® 10 mg daily for five days. If the prolactin level is high, a pituitary tumor should be ruled out through sella polytomography or computed tomography (CT). The diagnosis of anovulation may be made if the patient demonstrates normal prolactin levels and a positive response to progesterone, eg, menstrual bleeding.

In a patient with normal prolactin levels and no response to progesterone and estrogen/progesterone, a withdrawal test should be performed. While the failure to bleed suggests a pathological condition of the upper genital tract, such as uterine scarring, the presence of bleeding indicates primary ovarian failure or pituitary failure.

Since this patient responded to the progesterone withdrawal test, anovulation was presumed to be the cause of the amenorrhea.

Presented at the Annual Meeting of the Rhode Island Chapter, American College of Physicians, May 18, 1983.

Fred Brosco, BA, is a member of the Brown University Program in Medicine Class of 1984, Providence, Rhode Island.

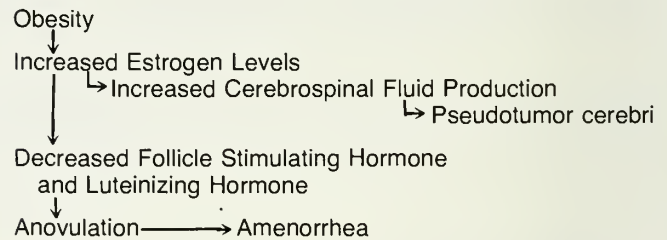
Tom J. Wachtel, MD, is Director, Medical Primary Care Unit, Rhode Island Hospital and Assistant Professor of Community Health, Brown University Program in Medicine, Providence, Rhode Island.

The neurologic symptoms of the patient were consistent with the benign intracranial hypertension (BIH) syndrome, or pseudotumor cerebri, which is characterized by intracranial pressure without focal neurologic deficits.^{1, 2} This syndrome, which may be hereditary, occurs mostly in young obese women with menstrual irregularities. Associated conditions include hyperthyroidism, hypothyroidism, hypoparathyroidism, hypoadrenalism, pregnancy, systemic disease, and abnormal levels of vitamin A. It may result from the ingestion of such drugs also as tetracycline, oral contraceptives, steroids, nalidixic acid, and nitro-furantoin. The possible mechanisms of BIH include increased blood volume and the delayed absorption or increased production of cerebrospinal fluid (CSF).³⁻⁴ It often presents with headaches, especially with coughing or straining; visual disturbances; and less commonly, diplopia, syncope, seizure, dizziness, or nausea.

The physical signs include papilledema in a patient who looks well, normal visual fields or an increased blind spot, decreased visual acuity, and, infrequently, sixth nerve palsy. The workup should begin with a CT scan and, if normal, be followed by a lumbar puncture to check for increased cerebrospinal fluid pressure (200 mm H₂O) with normal cell count, protein, and glucose. Other tests such as electroencephalogram, arteriogram, brain scan, and sella tomograms would all be normal and need not be done. The differential diagnoses include optic and retrobulbar neuritis, which can be distinguished from papilledema upon funduscopic examination by an experienced clinician. Such cerebral space-occupying lesions as brain tumors or abscesses can be excluded by CT scan.

While headaches usually abate in three to 12 months, visual acuity and field defects may persist. There is a 10 per cent recurrence rate during the first year, and rarely, the empty sella syndrome may supervene.

Table 1. — Pathophysiologic Relationship Between Pseudotumor Cerebri and Amenorrhea



The treatment of mild cases without visual symptoms consists of repeated lumbar punctures with removal of 15 to 50 ml of cerebrospinal fluid. More severe cases require treatment with steroids (16 mg dexamethasone daily). Although relief of symptoms begins within one week, the steroids alone will not alter CSF volume and a drainage by spinal tap should be performed as well. Patients who do not respond to medical therapy may require a lumboperitoneal shunt.⁴⁻⁵ The relationship of benign intracranial hypertension and amenorrhea is illustrated in Table 1.⁶

The CT scan and lumbar puncture results in our patient were consistent with pseudotumor cerebri.

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HAVE YOU HEARD? . . .

A recently-completed study by a group of university-based physicians and the St Paul Fire and Marine Insurance Company shows that many obstetrical malpractice claims might have been avoided if pregnancy risks had been properly identified and better managed. During the study of claims closed between 1980 and 1982, a team of five obstetricians from the University of Minnesota performed a retrospective review of 220 cases. While noting that further prospective studies will be necessary to validate the results, the researchers found that major pregnancy risks in the claims studied were often unrecognized or incorrectly managed by the physician. In 1983, in comparison to the previous four years, the insurance company experienced a 50 per cent increase in the number of claims filed for alleged mismanagement of pregnancy.

In a related development, the American College of Obstetrics and Gynecology also has reported that a significant percentage of its membership has eliminated the delivery of obstetrical services because of the threat of litigation and increasing costs of professional liability coverage.

• • •

The American Diabetes Association (ADA) recently launched a \$4 million public health education program designed to reach all primary care physicians in the US during the next two years. The ADA Clinical Education Program will focus on Type II (non-insulin dependent) diabetes which affects 90 per cent of the 11 million Americans suffering from the disease. An estimated 5 million of these cases remain undetected. It is projected that more than 600,000 patients will be diagnosed in 1984.

The program began in April with a teleconference involving approximately 20,000 physicians in 24 cities. Believed to be the largest meeting coordinated by any health organization, the seminar was transmitted by satellite to an audience of family physicians, internists, general practitioners, gynecologists, osteopathic physicians, and allied health professionals. During the next two years, numerous regional and local seminars will be conducted for similar groups. The program will emphasize the importance of initiating treatment of the 5 million undiagnosed diabetic Americans, especially those at high risk. These

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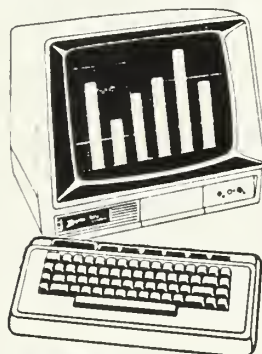
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include persons who are more than 40 years old, overweight, and who have a family history of diabetes; blacks; Hispanics; American Indians; and women.

As part of the program, the association also has published *The Physician's Guide to Type II Diabetes: Diagnosis and Treatment*, designed as a "working reference manual" for practicing physicians.

• • •

Pharmacies in the Northeastern and mid-Atlantic states recently introduced the Today Vaginal Contraceptive Sponge,[®] a new over-the-counter vaginal contraceptive which reportedly is comparable to the diaphragm in safety and effectiveness. Developed by the VLI Corporation, the sponge is made of a special polyurethane and contains 1 g nonoxynol-9. The sponge, designed for 24 hours continuous wear, is moistened with water to activate the spermicide and inserted by hand, comparable to a diaphragm. The walls of the vagina hold the sponge in place and the dimpled concave surface fits around the cervix. It is removed by pulling on an attached loop. The contraceptive effects begin immediately after insertion and remain for up to 24 hours without additional preparation.

Clinical trials, according to the company, were initiated in 1976 and were conducted at 27 centers in 11 countries, including 13 in the US. More than 2,000 women participated in the clinical tests. Company officials said that the sponge does not support the growth of *Staph aureus*, believed to be responsible for the toxic shock syndrome.

• • •

Some children may hate school because of emotional abuse from their teachers, according to a report in the March 1984 issue of the *American Journal of Diseases of Children*. Researchers from the University of Colorado School of Medicine describe marked behavior and personality changes among 17 third- and fourth-grade children who had been assigned to a new teacher. Such changes included excessive worry about school performance, moves from positive to negative self-perceptions, expressed hatred of school, and the onset of headaches, stomach aches, nightmares, and withdrawal.

Parents soon discovered that the real problem was not related to the adjustment capabilities of the youngsters, but to the emotionally abusive

teacher. Although the school administration initially discounted the situation, the teacher finally was removed and symptoms among 15 of the 17 children disappeared within two weeks. The other two children required psychiatric therapy to help rebuild their self-esteem. The researchers point out that the children acted out their problems in the safe environments of their homes, which made many parents originally suspect that the source of the problem was closer to home. The children, however, were venting emotions after struggling to be "well behaved" in the oppressive environment of the school room.

• • •

Near-total gastric bypass appears to be an effective operation for weight control of morbidly obese patients, according to a paper in the March 1984 issue of *Archives of Surgery*. Doctor Charles E. Hartford of the Crozer-Chester (PA) Medical Center reports on the results of 50 patients who underwent gastric bypass surgery in which the gastric pouch, or stomach, was made only large enough to permit a bypass connection with a portion of the small intestine. The mean weight loss 18 months after the operation was 55 kg, and mean excess weight loss was 70 per cent. Attributing the success of the procedure to the smallness of the pouch, Hartford postulates that a near-total gastric bypass should "virtually eliminate the need for revision because of a too-large pouch or a staple line failure." The patients were followed for three years after the operation.

• • •

The General Electric Research and Development Center in Schenectady, New York recently reported on its research with nuclear magnetic resonance (NMR), which uses radio, rather than x-ray, waves to look into the body. Scientists at the Center recently performed what are believed to be the world's first chemical analyses of the head and torso with the Center's NMR system. The system, which is based on superconducting magnets, also has been used to produce high-quality images of the human head. Researchers hope that the new technique ultimately will help doctors distinguish between benign and malignant tumors and detect conditions which could lead to myocardial infarctions and strokes.

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A new bone staple system from the Orthopedic Products Division of 3M includes a staple designed to resist staple "back-out" and a unique staple driver that allows full insertion without removing the driver. The new 3M Bone Staple System® can be used for all current staple applications, including fragment fixation, tendon and ligament repair, ligament repositioning, control of bone growth, surgical fusion of a joint, and osteotomy. The specially-designed staple, made of a chromecobalt-molybdenum alloy, has been shown in laboratory tests to be more resistant to "back-out" from vertical and lateral pressure than other staples.

• • •

Implant Technologies, Inc recently announced the development of a new tracheostomy tube which allows ventilator-dependent patients to speak clearly. The COMMUNitrach 1® tracheostomy tube allows patients to talk with near normal speech while the tube establishes and maintains an airway. Air for speaking is provided by a separate independent air source.

• • •

Researchers at the General Electric Research and Development Center have developed a new technique to culture large amounts of mammalian cells for medical research. The cells are grown on tiny droplets of oil suspended in a watery solution containing protein and other nutrients. The cells cling to the surfaces of the oil droplets, where they are nourished by the surrounding protein-rich "soup." Until now, mammalian cells have been cultured mainly on flat surfaces in plates or dishes flooded with a protein-rich solution. Because this approach re-

quires large amounts of space, biologists have sought other techniques.

Mammalian cells are required in the development and production of vaccines and hard-to-obtain substances such as human growth hormone, interferon, and monoclonal antibodies. Another potential application for this new development is the cultivation of cancer cells for tumor research.

• • •

The General Electric Company recently introduced a new, battery-powered x-ray film system designed to serve a full range of routine diagnostic radiographic procedures. The Technamatic® system, which delivers up to 1,000 radiographs on a single battery charge, consists of a generator, battery pack, x-ray tube and stand, and patient cart. It facilitates examination of virtually all anatomical areas. The self-contained unit, according to the manufacturer, is particularly suitable for basic care facilities in underdeveloped areas where the power supply is unstable.

• • •

Acuson recently announced development of its new ultrasound system, the Acuson 128®, which provides "unprecedented" image quality for medical diagnosis. The Acuson 128 is a real-time ultrasound system which produces images of internal organs, in motion, with clarity and detail. Because the system's high resolving power enables the physician to recognize and easily differentiate major tissue types, earlier and more accurate diagnoses will be possible. In addition, fetuses can be monitored for potential abnormalities at a much earlier stage of development.

• • •

SmithKline Diagnostics recently offered patient education materials on colorectal cancer to physicians. The packages include a table-top holder with SKD's Hemoccult® booklets which discuss colorectal cancer incidence, risk factors, and the value of the Hemoccult® test for fecal occult blood in screening for this disease. The material can be ordered from SmithKline Diagnostics, Promotional Services Department, PO Box 51947, Sunnyvale, California 94086 (1-800-538-1581).

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lem," a national telephone information and referral center has been opened at Fair Oaks Hospital, Summit, New Jersey to help cocaine addicts locate treatment. The toll-free number, 1-800-262-2463, connects physicians, cocaine users, family, or friends, to a staff of cocaine rehabilitation experts at Fair Oaks Hospital. The psychiatric hospital is linked to treatment centers, hospitals, and physicians in every state. The caller can have questions answered or be referred to the nearest treatment facility or physician without fear of losing anonymity.

• • •

A cooperative venture between the Israeli-based Omikron Scientific, Ltd and the University of Southern California may result in the development of an artificial pancreas by 1985. The device is intended to regulate the amount of insulin absorbed by diabetic patients to avoid improper dosages. The test device includes four parts: an element for measuring blood glucose levels, a micro-computer to determine how much insulin is required, an insulin reservoir, and a hydraulic pump. For test purposes, the unit is worn externally although scientists are planning ultimately to develop an implantable artificial pancreas.

• • •

The National Hemophilia Foundation now is accepting applications for the Judith Graham Pool Postgraduate Research Fellowships in Hemophilia. Grants of up to \$20,000 are available for clinical or basic research in the areas of biochemical, genetic, hematologic, orthopedic, psychiatric, or dental aspects of the hemophilias or Von Willebrand's disease. The research focus also may be on the rehabilitative, therapeutic, or social features of these disorders. Grant applications and additional information are available from the National Hemophilia Foundation, 19 West 34th Street, Suite 1024, New York, New York 10001.

• • •

The Upjohn Company has published a comprehensive patient information brochure on "Motrin Tablets (ibuprofen) . . . a medication to help relieve your arthritis."

The brochure is designed to reinforce information presented by the patient's physician, improve communication between patients and physicians, and encourage compliance with treatment regimens. The pamphlet explains that

Motrin® Tablets reduce pain, inflammation, and swelling without the dangers of addiction or potential problems from long-term corticosteroid use. It also discusses side effects that might be experienced so that patients can discuss them with their physicians. The booklets are available from Upjohn sales representatives.



Instromedix, Inc recently developed the Life-Signs Receiving System®, a transtelephonic arrhythmia surveillance system designed to help physicians monitor transient arrhythmias, drug dosage titration, and post-myocardial infarction conditions. The system includes easy-to-use transmitters and provides linkage with other Instromedix products. The company's Tape-A-Trace® 2400 automatically receives, records, and stores transtelephonic patient messages and electrocardiograms, helping physicians maintain contact with patients, and freeing technicians and nurses for other tasks. Instromedix, Inc., based in Beaverton, Oregon, develops and manufactures microprocessor-based cardiac diagnostic equipment to monitor heart conditions and pacemakers.



Researchers at the University of Cincinnati Medical School have reported successful results from a limited study of sucrose polyester, a substitute for fat that reportedly contains no calories and is indistinguishable in taste from common dietary fat. The substance, patented by Proctor & Gamble, is a nonabsorbable mixture of hexa-, hepta-, and octa-fatty acid esters of sucrose with physical properties similar to those of conventional common dietary fats. It currently is classified as an experimental drug. If the substance is approved by the FDA, a prescription will be required for its use.



The Orthopedic Products Division of the 3M Company recently developed a prosthesis for use in hip endoprosthetic procedures and total hip replacement. The new device — called the Bate-man UPFII Universal Proximal Femur® — features a bipolar design which permits universal articulation at the inner bearing to help preserve the acetabulum. The frictional differential between the 22mm inner bearing and outer bearings has been increased, limiting motion in the acetabulum. The assembly also is convertible to a 22mm total hip without moving the femoral component and with minimal patient trauma.

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Abbreviations: The *Journal* attempts to avoid the use of jargon and abbreviations. All abbreviations, especially of laboratory and diagnostic procedures, must be identified in the text.

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It is rarely desirable to include a complete review of the literature in the references. An alphabetized bibliography is to be used only when the listing is of books suggested for supplementary reading.

References

1. Stone PH, Turri ZG, Muller JE. Efficacy of nifedipine therapy for refractory angina pectoris. *Am Heart J* 104:672-681, September 1982
2. Antman E, Muller J, Goldberg S, et al. Nifedipine therapy for coronary artery spasm. Experience in 127 patients. *N Engl J Med* 302:1269-1273, June 5, 1980

BRIEF SUMMARY

PROCARDIA* (nifedipine) CAPSULES

For Oral Use

INDICATIONS AND USAGE: **I. Vasospastic Angina:** PROCARDIA (nifedipine) is indicated for the management of vasospastic angina confirmed by any of the following criteria: 1) classical pattern of angina at rest accompanied by ST segment elevation; 2) angina or coronary artery spasm provoked by ergonovine; or 3) angiographically demonstrated coronary artery spasm. In those patients who have had angiography, the presence of significant fixed obstructive disease is not incompatible with the diagnosis of vasospastic angina, provided that the above criteria are satisfied. PROCARDIA may also be used where the clinical presentation suggests a possible vasospastic component but where vasospasm has not been confirmed, e.g., where pain has a variable threshold on exertion or in unstable angina where electrocardiographic findings are compatible with intermittent vasospasm, or when angina is refractory to nitrates and/or adequate doses of beta blockers.

II. Chronic Stable Angina (Classical Effort Associated Angina): PROCARDIA is indicated for the management of chronic stable angina effort associated anginal without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

In chronic stable angina (effort associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in those patients are incomplete.

Controlled studies in small numbers of patients suggest concomitant use of PROCARDIA and beta blocking agents may be beneficial in patients with chronic stable angina, but available information is not sufficient to predict with confidence the effects of concurrent treatment, especially in patients with compromised left ventricular function or cardiac conduction abnormalities. When introducing such concomitant therapy, care must be taken to monitor blood pressure closely since severe hypotension can occur from the combined effects of the drugs. (See Warnings.)

CONTRAINDICATIONS

Known hypersensitivity reaction to PROCARDIA
WARNINGS: Excessive Hypotension: Although in most patients the hypotensive effect of PROCARDIA is modest and well tolerated, occasional patients have had excessive and poorly tolerated hypotension. These responses have usually occurred during initial titration or at the time of subsequent upward dosage adjustment, and may be more likely in patients on concomitant beta blockers.

Severe hypotension and/or increased fluid volume requirements have been reported in patients receiving PROCARDIA together with a beta blocking agent who underwent coronary artery bypass surgery using high dose tetranylin anesthesia. The interaction with high dose tetranylin appears to be due to the combination of PROCARDIA and a beta blocker, but the possibility that it may occur with PROCARDIA alone, with low doses of tetranylin, in other surgical procedures, or with other narcotic analgesics cannot be ruled out. In PROCARDIA treated patients where surgery using high dose tetranylin anesthesia is contemplated, the physician should be aware of these potential problems and if the patient's condition permits, sufficient time (at least 36 hours) should be allowed for PROCARDIA to be washed out of the body prior to surgery.

Increased Angina: Occasional patients have developed well documented increased frequency, duration or severity of angina on starting PROCARDIA or at the time of dosage increases. The mechanism of this response is not established but could result from decreased coronary perfusion associated with decreased diastolic pressure with increased heart rate, or from increased demand resulting from increased heart rate alone.

Beta Blocker Withdrawal: Patients recently withdrawn from beta blockers may develop a withdrawal syndrome with increased angina, probably related to increased sensitivity to catecholamines. Initiation of PROCARDIA treatment will not prevent this occurrence and might be expected to exacerbate it by provoking reflex catecholamine release. There have been occasional reports of increased angina in a setting of beta blocker withdrawal and PROCARDIA initiation. It is important to taper beta blockers if possible, rather than stopping them abruptly before beginning PROCARDIA.

Congestive Heart Failure: Rarely, patients usually receiving a beta blocker have developed heart failure after beginning PROCARDIA. Patients with tight aortic stenosis may be at greater risk for such an event.

PRECAUTIONS: General Hypotension: Because PROCARDIA decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of PROCARDIA is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure. (See Warnings.)

Peripheral edema: Mild to moderate peripheral edema, typically associated with arterial vasodilation and not due to left ventricular dysfunction, occurs in about one in ten patients treated with PROCARDIA. This edema occurs primarily in the lower extremities and usually responds to diuretic therapy. With patients whose angina is complicated by congestive heart failure, care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

Drug interactions: Beta adrenergic blocking agents. (See Indications and Warnings.) Experience in over 1400 patients in a non-comparative clinical trial has shown that concomitant administration of PROCARDIA and beta blocking agents is usually well tolerated, but there have been occasional reports suggesting that the combination may increase the likelihood of congestive heart failure, severe hypotension or exacerbation of angina.

Long acting nitrates. PROCARDIA may be safely co-administered with nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

Digitalis. Administration of PROCARDIA with digoxin increased digoxin levels in nine of twelve normal volunteers. The average increase was 45%. Another investigator found no increase in digoxin levels in thirteen patients with coronary artery disease. In an uncontrolled study of over two hundred patients with congestive heart failure during which digoxin blood levels were not measured, digitalis toxicity was not observed. Since there have been isolated reports of patients with elevated digoxin levels, it is recommended that digoxin levels be monitored when initiating, adjusting, and discontinuing PROCARDIA to avoid possible over- or under-digitalization.

Carcinogenesis, mutagenesis, impairment of fertility. When given to rats prior to mating, nifedipine caused reduced fertility at a dose approximately 30 times the maximum recommended human dose.

Pregnancy. Category C. Please see full prescribing information with reference to teratogenicity in rats, embryotoxicity in rats, mice and rabbits, and abnormalities in monkeys.

ADVERSE REACTIONS: The most common adverse events include dizziness or light-headedness, peripheral edema, nausea, weakness, headache and flushing each occurring in about 10% of patients; transient hypotension in about 5%; palpitation in about 2%; and syncope in about 0.5%. Syncopal episodes did not recur with reduction in the dose of PROCARDIA or concomitant antianginal medication. Additionally the following have been reported: muscle cramps, nervousness, dyspnea nasal and chest congestion, diarrhea, constipation, inflammation, joint stiffness, shakiness, sleep disturbances, blurred vision, difficulties in balance, dermatitis, pruritus, urticaria, fever, sweating, chills, and sexual difficulties. Very rarely, introduction of PROCARDIA therapy was associated with an increase in anginal pain, possibly due to associated hypotension.

In addition, more serious adverse events were observed, not readily distinguishable from the natural history of the disease in these patients. It remains possible, however, that some or many of these events were drug related. Myocardial infarction occurred in about 4% of patients and congestive heart failure or pulmonary edema in about 2%. Ventricular arrhythmias or conduction disturbances each occurred in fewer than 0.5% of patients.

Laboratory Tests: Rare, mild to moderate, transient elevations of enzymes such as alkaline phosphatase, CPK, LOH, SGOT, and SGPT have been noted, and a single incident of significantly elevated transaminases and alkaline phosphatase was seen in a patient with a history of gall bladder disease after about eleven months of nifedipine therapy. The relationship to PROCARDIA therapy is uncertain. These laboratory abnormalities have rarely been associated with clinical symptoms. Cholestasis, possibly due to PROCARDIA therapy, has been reported twice in the extensive world literature.

HOW SUPPLIED: Each orange, soft gelatin PROCARDIA CAPSULE contains 10 mg of nifedipine. PROCARDIA CAPSULES are supplied in bottles of 100 (NDC 0069-2600-66), 300 (NDC 0069-2600-72), and unit dose (10x10) (NDC 0069-2600-41). The capsules should be protected from light and moisture and stored at controlled room temperature 59 to 77°F (15 to 25°C) in the manufacturer's original container.

More detailed professional information available on request

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Rhode Island Medical Journal

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Quotes from an unsolicited letter received by Pfizer from an angina patient. While this patient's experience is representative of many unsolicited comments received, not all patients will respond to Procardia nor will they all respond to the same degree.

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*Procardia is indicated for the management of:

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- 2) Angina where the clinical presentation suggests a possible vasospastic component.
- 3) Chronic stable angina without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or nitrates or who cannot tolerate these agents. In chronic stable angina (effort-associated angina) PROCARDIA has been effective in controlled trials of up to eight weeks' duration in reducing angina frequency and increasing exercise tolerance, but confirmation of sustained effectiveness and evaluation of long-term safety in these patients are incomplete.

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Caution patients about driving, operating hazardous machinery or drinking alcohol during therapy. Limit dose to 15 mg in elderly or debilitated patients. Contraindicated during pregnancy.

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References: 1. Kales J et al: *Clin Pharmacol Ther* 12:691-697, Jul-Aug 1971. 2. Kales A et al: *Clin Pharmacol Ther* 18:356-363, Sep 1975. 3. Kales A et al: *Clin Pharmacol Ther* 19:576-583, May 1976. 4. Kales A et al: *Clin Pharmacol Ther* 32:781-788, Dec 1982. 5. Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. 6. Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. 7. Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther* 21:355-361, Mar 1977. 8. Zimmerman AM: *Curr Ther Res* 13:18-22, Jan 1971. 9. Amrein R et al: *Drugs Exp Clin Res* 9(1):85-99, 1983. 10. Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. 11. Greenblatt DJ et al: *Sleep* 5(Suppl 1):S18-S27, 1982. 12. Kales A et al: *Pharmacology* 26:121-137, 1983.

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Contraindications: Known hypersensitivity to flurazepam HCl; pregnancy. Benzodiazepines may cause fetal damage when administered during pregnancy. Several studies suggest an increased risk of congenital malformations associated with benzodiazepine use during the first trimester. Warn patients of the potential risks to the fetus should the possibility of becoming pregnant exist while receiving flurazepam. Instruct patient to discontinue drug prior to becoming pregnant. Consider the possibility of pregnancy prior to instituting therapy.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, light-headedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. **Adults:** 30 mg usual dosage, 15 mg may suffice in some patients. **Elderly or debilitated patients:** 15 mg recommended initially until response is determined.

Supplied: Capsules containing 15 mg or 30 mg flurazepam HCl.



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See preceding page for references and summary of product information.
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Rhode Island Medical Journal

June 1984
Volume 67, Number 6

DISPLAY
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The State House, Providence, Rhode Island

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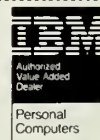
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THE RHODE ISLAND MEDICAL SOCIETY
JUNE 1984

JUNE 1984

RHODE ISLAND GENERAL ASSEMBLY ADJOURNS

After a last-minute deadlock over the state's budget, the Rhode Island General Assembly adjourned for the year on May 11, almost a week later than scheduled. During the 1984 session, the lawmakers considered nearly 200 bills on health-related matters. After reviewing these proposals, the RIMS Public Laws Committee, under the leadership of Dr Peter D.T. Clarisse, recommended that the Society focus its efforts on 40 bills.

In his report to the May 23 annual session of the RIMS House of Delegates, Dr Clarisse said that four major issues emerged during the 1984 session:

- Malpractice: The Society successfully introduced a package of five bills intended to alleviate the growing malpractice crisis. Sponsored by Sen John Revens (D, Warwick), the bills, if passed, would have established guidelines for the structured payment of award settlements, amended the collateral source rule, reduced the interest on awards, limited awards for pain and suffering, and established qualifications for expert witnesses.

Instead of acting on the five-bill package, the Senate Judiciary Committee laid the groundwork for future reform of the tort system by creating a legislative commission to study the problem. The commission must report its findings by January 1, 1985. The malpractice problem, Dr Clarisse told the House of Delegates, will be "the Society's major priority during the 1985 session."

For information on reform initiatives on the federal level, see page 268 of this Journal.

- Optometric drug use: As the result of combined efforts by the Society, the RI Ophthalmological Society, and the Brown

GENERAL ASSEMBLY (continued)

University Program in Medicine, the House Corporations Committee refused to act on a bill which would have permitted optometrists to use therapeutic drugs to treat ocular disease. While optometrists in 37 states, including Rhode Island, may use drugs for diagnostic purposes, prescription of therapeutic agents is permitted only in West Virginia and North Carolina.

Dr Milton W. Hamolsky, Physician-in-Chief, Department of Medicine, Rhode Island Hospital, and RIMS Secretary, told the legislators that many ocular conditions may be manifestations of general systemic disease which optometrists are not trained to recognize. Also speaking against the bill were Drs. David S. Greer, Dean, Brown University Program in Medicine; Robert S.L. Kinder, Chief of Ophthalmology, Rhode Island Hospital; H. Denman Scott, Deputy Director, RI Department of Health; Thomas Hutchinson, Harvard Medical School; and Alfred Lemoine, a Kansas City ophthalmologist.

The successful legislative strategy was organized by RI Ophthalmological Society President Dr Y. Jacob Schinazi.

- Physician's Assistants: The House Health, Education, and Welfare Committee considered two bills which, if approved, would have expanded the scope of practice of PAs. In testimony before the House HEW Committee, RIMS President Dr Charles P. Shoemaker, Jr. supported a bill introduced by Brown University which would have created a limited exemption from the supervision requirements of the existing PA statute for PAs in university settings. Approved by the Committee, the bill later was amended on the House floor to encompass the broader provisions of a second bill. Drs Shoemaker and Charles E. Millard

RIMS past president, testified before the Senate HEW Committee against the amended version. The Society emphasized the possible public health threat which would result from "expanding the scope of PAs' practices by legislative fiat rather than through education and training." As a result of mounting opposition, the Senate committee refused to act and the bill died for the year.

Living wills: Representing the Society and the RI District Branch of the American Psychiatric Association, Dr James R. McCartney testified in support of S 0009, sponsored by Sen Lila Sapinsley. If enacted, S 0009 would have provided a mechanism for a "living will," permitting physicians to withhold extraordinary life-sustaining measures. Reported favorably out of the Senate Judiciary Committee, the bill suffered defeat on the Senate floor. In its place, the General Assembly approved a 1983 House bill which creates a special commission to review the issue.

Doctor Clarisse told the RIMS delegates that the Society also played an active role in other bills on a broad spectrum of issues, including the establishment of a 911 emergency telephone system, revisions in the statute of limitations, changes in the mental health code, and worker's compensation insurance. The Society also supported the recently-approved law which raises the minimum drinking age to 21 years effective this July.

A detailed analysis of the 1984 legislative session will be published in the July issue of this Journal.

SOCIETY STRENGTHENS LIAISON WITH CONGRESSIONAL OFFICES

The RIMS Executive Committee met May 7 with Christie Ferguson, a legislative aide from Sen John Chafee's office, to discuss the fiscal problems facing the Medicare program and possible alleviation of the malpractice crisis. Drs Frances P. Conklin, President, Providence Medical Association; David S. Greer, Dean, Brown University Program in Medicine; and John J. Cunningham, RIMS Delegate to the American Medical Associa-

tion, also participated in the three-hour session.

Many of the problems identified during the broad-ranging discussion fell into one of three areas: 1) the appropriate reimbursement for physician services; 2) the impact of the malpractice crisis on the Medicare program and other medical services; and 3) anti-trust considerations affecting medical practice. Additional meetings will be scheduled to work on potential solutions for the Senator's consideration.

The Society also will participate in a June 16 conference organized by Sen Claiborne Pell for senior citizens at the Warwick campus of the Community College of Rhode Island. Nearly 1,000 persons are expected to attend the day-long meeting on Medicare. Representing the Society, past president Dr Charles E. Millard will address the problem of how patients can control medical costs most effectively.

JCAH TO SURVEY NINE RHODE ISLAND HOSPITALS

Nine hospitals are scheduled this month to receive site visits from the Joint Commission on the Accreditation of Hospitals (JCAH). These facilities include Notre Dame Hospital, South County Hospital, Newport Hospital, Newport Naval Medical Center, Pawtucket Memorial Hospital, Rhode Island Hospital, Rhode Island Medical Center, Woonsocket Hospital, and Zambarano Memorial Hospital.

None of the affected hospitals will be subject to the revised medical staff standards approved by JCAH last December after nearly three years of debate. At issue were provisions for recognition of non-physician providers. While the new guidelines provide qualified non-physician providers with access to hospitals, the medical staff retains ultimate responsibility for the provision of patient care. The proposed references in an earlier draft to dentists, podiatrists, and other limited-license practitioners were eliminated from the final version. The new standards will become effective July 1, 1984 for survey purposes although they will not be used for accreditation evaluation purposes until next January.

DR HEALEY INSTALLED AS SOCIETY PRESIDENT

Dr Paul J.M. Healey, a Pawtucket surgeon, was installed as the Society's 126th president at the May 23 annual general membership meeting. He succeeds Dr Charles P. Shoemaker, Jr. of Newport.

A native of Pawtucket, Dr Healey received his medical degree from Boston University School of Medicine and completed his internship and residency training at Boston City Hospital. He is Chief of Vascular Surgery, The Memorial Hospital, Pawtucket; and Assistant Clinical Professor of Surgery, Boston University School of Medicine. Long involved in medical society activities, Dr Healey has served as an officer of the Pawtucket Medical Association and Providence Surgical Society, and as a director of Blue Cross & Blue Shield of Rhode Island. He presently is the Governor of the American College of Surgeons for Rhode Island.

The new president-elect is Dr Leonard S. Staudinger, a Woonsocket surgeon who most recently served the Society as vice-president from 1982-1983. Dr Staudinger will assume the presidency next May.

Other officers for 1984-1985 include Drs Melvyn M. Gelch, a Providence neurosurgeon, vice-president; Kenneth E. Liffmann, a Providence orthopedic surgeon, treasurer; and Milton W. Hamolsky, a Providence internist, secretary.

TWO RIMS MEMBERS HONORED AT ANNUAL MEETING

The many accomplishments of two Rhode Island physicians were recognized at the Society's May 23 Annual Dinner. The dinner was held in conjunction with the 173rd Annual Meeting, held at the Providence Marriott Hotel, Providence.

Dr Henry T. Randall, Surgeon-in-Chief Emeritus, Rhode Island Hospital, received the 1984 Charles L. Hill Award for Distinguished Service. Dr Randall, who until recently chaired the Annual Meeting Committee (1981-1983), was honored for his "endeavors on behalf of the Society and his significant contributions to the quality of medical care in Rhode Island."

ANNUAL MEETING (continued)

Dr Joseph E. Cannon, who retires in July after 23 years as Director of the Rhode Island Department of Health, was praised for his "commitment to professionalism and the spirit of scientific inquiry which has established the state's reputation as a leader in public health."

"All Rhode Island citizens," RIMS President Dr Charles P. Shoemaker told the retiring director, "have benefited from your dedicated stewardship."

PERIPATETICS

Society members in the news this month include:

- The Rhode Island District Branch of the American Psychiatric Association recently elected the following officers for the coming year: Drs William Braden, President; Lowell J. Rubin, President-Elect; Paul Sapir, Immediate Past President; and Robert G.M. Johnston, Secretary-Treasurer.
- Dr Richard A. Carleton, physician-in-chief and chief of cardiology at The Memorial Hospital, Pawtucket, recently was appointed to a three-year term on the advisory council of the National Heart, Lung, and Blood Institute. The appointment was made by US Health and Human Services Secretary Margaret Heckler. The 18-member committee advises the DHHS Secretary and Congress on policy and research for cardiac, pulmonary, and hematologic disease, and funding for the Institute's budget.
- Newly elected to fellowship status in the American Academy of Pediatrics was Dr. David P. Fletcher, Warwick.
- Newly-appointed department chiefs at Newport Hospital include Drs. Peter D.T. Clarisse, radiology; Charles P. Shoemaker, Jr., surgery; Gerhard C. Meier, medicine; and Nasser Chahmirzadi, obstetrics and gynecology.
- Dr Israel Diamond, Providence, has been named to the editorial board of the Archives of Pathology.

HOW DO I UPDATE MY BLUE SHIELD PROFILE?

Blue Cross & Blue Shield of Rhode Island periodically sends profile worksheets to all physicians with Blue Shield profiles whether or not they have signed formal participation agreements. The worksheet shows the physician's current Blue Shield reimbursement for each procedure code at the time of the last revision and provides space for updated charge information.

You should follow the steps outlined below in reviewing your profile worksheet:

- Compare the Blue Shield allowance for each procedure with your current actual charge. If your actual charge and the Blue Shield allowance are the same, your charge is either less or the same as the Blue Shield allowance for physicians in your specialty and geographic area performing the same service.

If the reimbursement paid by Blue Shield is less than your actual charge, your charges may be higher than the Blue Shield allowance or may not have been updated.

- Update your profile to include both your new actual charge and those which remain unchanged, especially if the Blues' reimbursement is less than the unchanged charge.

The following situation may well occur if you do not update your profile. Our hypothetical Dr Jones charged \$15 for a routine hospital visit at a time when the Blue Shield allowance was \$10. He will continue to receive \$10, unless he updates his charges periodically, even if the Blue Shield allowance increases to \$25 and his actual charge is listed as \$15.

- Return your profile to Blue Cross & Blue Shield of Rhode Island via certified mail, return receipt requested, as soon as possible after receipt.

Profiles must be received at the Blues offices by March 31 so that physicians' charges are accurately reflected in the rate proposal submitted to the Department of Business Regulation.

- If you do not receive an acknowledgment from Blue Shield within ten days, you should call the Office of Professional Relations (401/272-8500) to make certain that it has been received.

A copy of the Blue Cross & Blue Shield publication, How-To, is available upon request from the Office of Professional Relations, 444 Westminster Mall, Providence, Rhode Island 02901. It addresses many of the questions physicians and their office staffs may have concerning reimbursement programs.

MORE ON DRGS . . .

As reported in the May 1984 Practice Management Question of the Month on diagnosis-group based reimbursement, physicians must certify that the principal and secondary diagnoses and procedures listed in the record are accurate. It also warns that intentional misrepresentation or fraud is "punishable by imprisonment, fine, or civil penalties." The AMA has requested a meeting with the Health Care Financing Administration over the wording. At least five state medical societies have submitted resolutions objecting to the requirement for the consideration of the AMA House of Delegates at its June meeting. At the request of the medical staff of South County Hospital, the RIMS Council will examine the issue.

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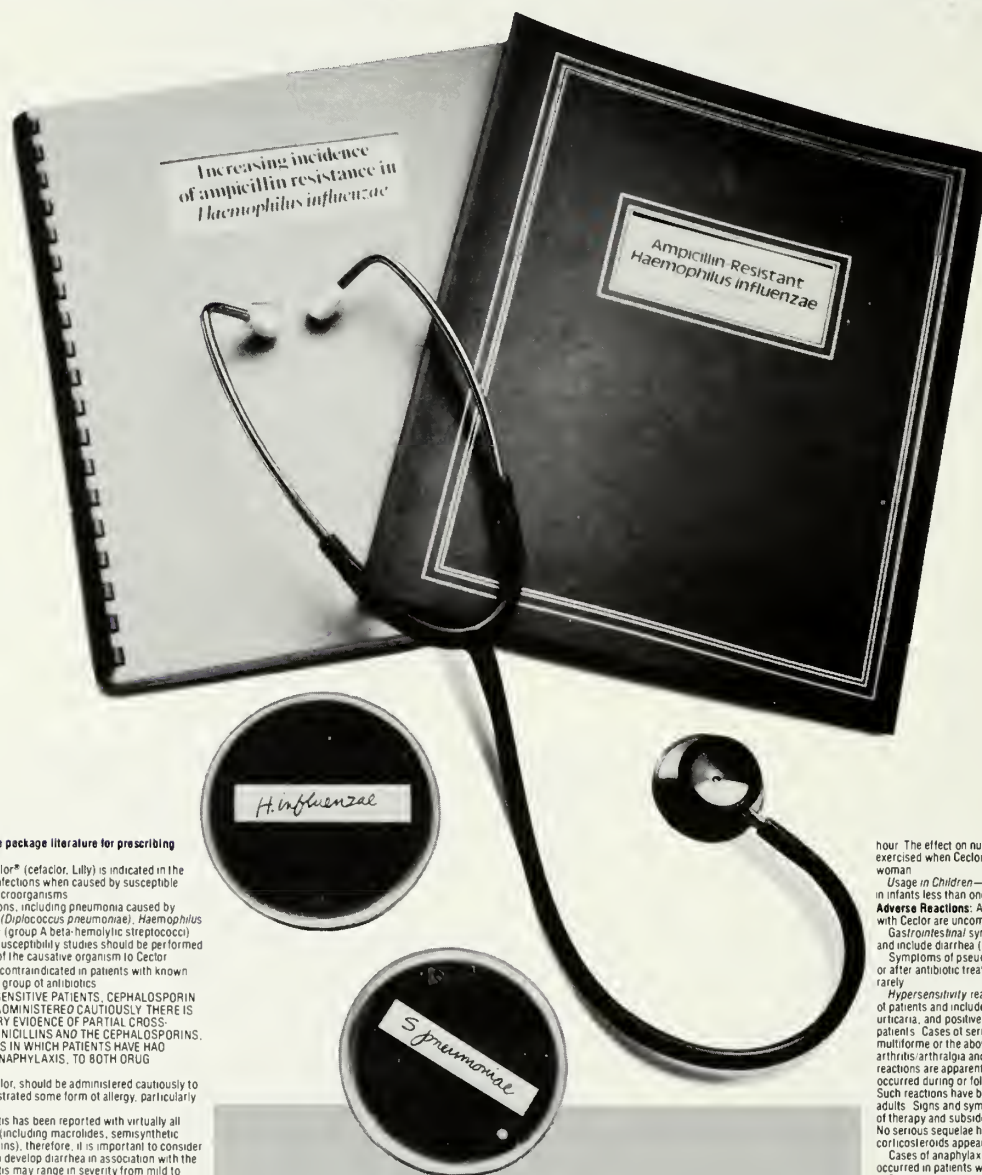
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An added complication... in the treatment of bacterial bronchitis*



Brief Summary. Consult the package literature for prescribing information.

Indications and Usage. Cefclor® (cefclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae* (*Diplococcus pneumoniae*), *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci). Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Cefclor.

Contraindication. Cefclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings. IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Cefclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics including macrolides, semisynthetic penicillins, and cephalosporins; therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: General Precautions—If an allergic reaction to Cefclor occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Cefclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antoglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Cefclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Cefclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinistix® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly). Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy—Pregnancy Category B.—Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Cefclor. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers.—Small amounts of Cefclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one

Some ampicillin-resistant strains of *Haemophilus influenzae*—a recognized complication of bacterial bronchitis*—are sensitive to treatment with Cefclor.¹⁻⁵

In clinical trials, patients with bacterial bronchitis due to susceptible strains of *Streptococcus pneumoniae*, *H. influenzae*, *S. pyogenes* (group A beta-hemolytic streptococci), or multiple organisms achieved a satisfactory clinical response with Cefclor.⁷

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hour. The effect on nursing infants is not known. Caution should be exercised when Cefclor® (cefclor, Lilly) is administered to a nursing woman.

Usage in Children.—Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions. Adverse effects considered related to therapy with Cefclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100), Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis, arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Cefclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of the therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome. Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain.—Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic.—Slight elevations of SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematologic.—Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal.—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

*Many authorities attribute acute infectious exacerbation of chronic bronchitis to either *S. pneumoniae* or *H. influenzae*.

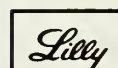
Note: Cefclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285. Eli Lilly Industries, Inc., Carolina, Puerto Rico 00630.

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JUA Experience Indicates that Malpractice Reform Is Still Imperative

Kenneth E. Liffmann, MD, FACS

It is especially fitting that the State House of the State of Rhode Island and Providence Plantations be depicted on the cover of this issue, which features an in-depth analysis of the malpractice crisis from several perspectives. The Society will continue to seek significant changes in the tort system when the Rhode Island General Assembly reconvenes next January. For more on this problem, see page 267.



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MARKETING UPDATE

Enrollment has shown another 30% increase in the month of May. Current enrollment is at 3965, up from 1781 on January 1, 1984 - a **120%** increase!

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Is the Autopsy Regaining Respectability?

The postmortem examination contributed mightily to the advance of medical knowledge during the nineteenth century and the early decades of the twentieth. Its educational value was brilliantly demonstrated by the likes of Richard Cabot and his peers who developed the clinical-pathological conference (CPC). The CPCs of the Massachusetts General Hospital, after three quarters of a century, are still an attractive and rewarding feature of our eminent contemporary, the *New England Journal of Medicine*. Despite its proven value in the advancement of medical science, the autopsy has been de-emphasized over the past twenty-five years at leading academic medical centers throughout the United States. The minimum autopsy rate of twenty per cent was, in a burst of questionable wisdom, eliminated by the Joint Commission on the Accreditation of Hospitals (JCAH) in the early 1960s as an accreditation requirement. The autopsy rate had exceeded 50 per cent in some teaching hospitals. As a result of the new climate, hospitals are now much less aggressive in urging house and attending staffs to request permission for autopsies.

This changed attitude was partly a result of waning enthusiasm on the part of pathologists for this extra burden upon their busy schedules and partly a result of hospital administrators' endeavors to reduce overhead costs. With the burgeoning of technological breakthroughs in diagnostic procedures, clinicians came to feel a lessening pressure to sharpen their skills in hands-on clinical diagnosis. The answer too often was "obvious" from the workup, surgery, or diagnostic studies during the unfolding of the case. Doctor Stephen A. Geller of Mount Sinai Hospital of New York, writing in the *Scientific American*, explains that many physicians feel that modern medical technologies provide more than adequate information regarding the causes of a pa-

tient's illness. It is a fact, however, that studies at major medical centers reveal discrepancy rates of up to 40 per cent between clinical and autopsy diagnoses of causes of death. Geller concedes that even at Mount Sinai during the past decade the discrepancy rate has been estimated to amount to fifteen to twenty per cent.

Geller has set forth several ways in which autopsies may provide invaluable medical information. They offer a rich source of material for research. The cardiotoxic effects of Adriamycin® were first demonstrated through autopsy material. Postmortem examination of oncology patients provides significant information concerning the pathophysiologic effects of chemotherapy. Two recent clinical entities, Legionnaire's disease and toxic shock syndrome, have been elucidated largely through autopsy studies. Other recent entities have been asbestosis, mesothelioma, pneumocystosis, adult respiratory distress syndrome, disseminated intravascular coagulopathy, angioimmunoblastic lymphadenopathy, and multifocal leukoencephalopathy. Most recently, autopsy studies have led to the identification of the acquired immune deficiency syndrome (AIDS). The postmortem materials from the "bubble boy" promise to reveal many further strange and illuminating facts concerning immune deficiency.

Recently autopsy studies of Alzheimer's disease and related senile disorders have been organized on a national scale. The Alzheimer's Disease and Related Disorders Association (ADRDA) has established an autopsy network to provide scientists with brain tissue for research. Autopsy material, for example, has indicated a curious link between Alzheimer's disease and Down's syndrome. A decline in the autopsy rate has inspired a series of letters to the *Journal of the American Medical Association* regarding the possible distor-

tion of statistics related to the declining incidence of myocardial infarction.

It is encouraging to observe this renewed interest in autopsies, and the JCAH has been urged in some quarters to restore a minimum requirement.

There are, however, influences working against this trend. The poor attendance of house and visiting staffs to the postmortem room and the apparent indifference of some pathologists are limiting factors, although autopsies are important educational exercises for pathology residents. An autopsy is said to cost the hospital about \$1,000. This is an overhead factor that most hospital administrators would gladly avoid, especial-

ly in this day of DRGs and other cost restraints. It has been said that death is the ultimate economy in health care. Superimposing a postmortem examination does indeed sacrifice some of this saving.

As Geller has pointed out, however, the autopsy is above all a learning experience. Through it, he states, "we can know the effects of our therapeutic efforts on the progress of disease and we can identify our failures in diagnosis" — an invaluable educational device for visiting staff, residents, and medical students alike. It is important that every effort be made to obtain autopsies and that the continuing decline in their numbers be reversed.

Seebert J. Goldowsky, MD

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Congress to Consider Malpractice Reform Legislation

Although the federal government traditionally has delegated the responsibility for insurance-related issues to state legislatures and local courts, there are positive indications that this "hands-off" approach to malpractice insurance may change in the near future. Representatives Henson Moore (R, Louisiana) and Richard Gephardt (D, Missouri) recently introduced a proposal which would radically change the way malpractice claims are handled.

Drafted by Jeffrey O'Connell, a recognized authority on no-fault automobile insurance from the University of Virginia, the Moore-Gephardt bill would apply a modified "no-fault" approach to patient care paid for by the federal government. These patients include Medicare beneficiaries, Medicaid recipients, military personnel, veterans, and federal employees. The Alternative Medical Liability Act, as the bill is formally known, would allow the provider to offer a settlement within six months of the occurrence of the alleged incident. The settlement is to include payment for such "net economic losses" as out-of-pocket expenses, reasonable legal charges, the

costs of medical care, lost wages, and rehabilitation expenses. Once the offer had been made, the patient would forfeit all rights to judicial review except to dispute the appropriateness of the settlement on economic grounds. There would be no provision for punitive damages or awards for "pain and suffering."

If no settlement offer is made, the case would be adjudicated under the current tort system. The patient would have full access to the courts and could seek punitive damages in addition to an award for economic losses. While an earlier draft of the bill transferred the burden of proof to the defendant, the current proposal leaves it with the plaintiff.

The bill gives the individual states the option of establishing their own liability systems as long as the federal criteria are satisfied. Only those states which had not acted by January 1, 1987 would be subject to its provisions. In a Washington, DC press conference held last month, Henson and Gephardt said that this stipulation should encourage the states to exceed federal requirements by applying the system to all patients and not only

to federal beneficiaries.

At the same press conference, the sponsors also emphasized the skyrocketing costs of the malpractice crisis. While no conclusive figures are available, a 1983 study by the American Medical Association reports that the total bill for malpractice premiums of the nation's physicians, their skilled employees, and hospitals last year reached an estimated \$3.5 billion. Not included in this figure is the estimated price tag for "defensive medicine" and other indirect costs associated with professional liability. Some experts have claimed that these indirect expenses may be responsible for as much as 30 per cent, or more than \$100 billion, of the total health care expenditures in the United States per year. According to one AMA survey, more than 40 per cent of all physicians in 1981 ordered additional diagnostic tests and 27 per cent performed therapeutic procedures solely to protect themselves against potential claims. Moore and Gephardt conceded that it was impossible to project the savings, if any, that would result from their proposal. Although legal and administrative costs would remain, the congressmen maintain that the determination of an economic loss is much less costly than assigning a dollar figure to the emotionally-charged concept

of "pain and suffering."

The proposal also has been subjected to other criticisms. Some have questioned the fairness and ultimate constitutionality of a system which singles out one group of patients, ie, federal beneficiaries. Other critics maintain that patients legally cannot be forced to give up their right to sue. Over the past decade, they contend, the courts have struck down similar legislative reforms, including such innovations as arbitration panels, limitations on awards for "pain and suffering," and caps on the total award size.

Despite these criticisms, the bill should be regarded as an encouraging sign that officials on the federal level are beginning to recognize the pervasive and devastating impact of the malpractice crisis. Hearings on the Moore-Gephardt bill have been scheduled for later this year before the US House Ways and Means Committee, and Senator Daniel Inouye (D, Hawaii) has introduced legislation which would establish screening panels. While no federal action on the malpractice problem is expected this year, the respected *Washington Report on Medicine and Health* recently predicted that malpractice reform legislation may well become a "priority item on the 1985 Congressional agenda."

Wendy J. Smith

IN MEMORIAM

Melvin D. Hoffman, MD (1925-1984)

The Publications Committee of the Rhode Island Medical Society and the Editorial Board and Editors of the *Rhode Island Medical Journal* wish to express their sorrow at the recent passing of Doctor Melvin D. Hoffman.

Doctor Hoffman served in the US Marine Corps during World War II. Maintaining a lifelong interest in the Boy Scouts, he was the medical director of Camp Yawgoog until his death. He also was actively involved in many community organizations and was a past chairman of the Interagency Council on Smoking of Rhode Island.

Long active in the Society, Doctor Hoffman

served as president during 1982-1983. At the time of his death, he was a member of the RIMS Executive Committee and chairman of the Mediation Committee, a member of the Rhode Island Board of Medical Review, and a representative to the AMA's Health Policy Agenda for the American People Committee. One of his most significant accomplishments on behalf of the Rhode Island Medical Society was his spearheading the recently-published *Guide to Physician Services*.

Doctor Hoffman will be remembered with respect and affection. We shall miss him greatly.

The Trustees of the Fiske Fund of the Rhode Island Medical Society are pleased to announce the

FISKE PRIZE FOR 1984

to be awarded for an original contribution on

"A Current Technological Innovation and Its Impact on Medicine"

The award is named after Caleb Fiske (1753-1834), who was a Rhode Island physician and judge, Army surgeon, and a descendent of Roger Williams. Since the prize was initiated in 1836, 86 awards have been made for original contributions. Previous recipients include Charles V. Chapin, Providence, internationally known for his research on public health; David King, Jr., Newport who received the award in 1836 for his paper on "Purpura Haemorrhagica: Its Causes and Treatment"; and Alton Oschner, New Orleans, who received the 1958 award for his paper entitled "Bronchogenic Carcinoma: Predisposing Causes."

The award for the 1984 Fiske Prize will be a maximum of \$2,500. The Trustees reserve the right to award one or more prizes. The competition is not restricted to physicians.

Guidelines:

- 1) The original and one copy must be submitted by August 15, 1984 to Marion Sabella, Secretary, Caleb Fiske Fund of the Rhode Island Medical Society, 106 Francis Street, Providence, Rhode Island 02903.
- 2) All papers must be double-spaced and should not exceed 10,000 words.
- 3) The award recipient must transfer copyright privileges to the Trustees of the Caleb Fiske Fund of the Rhode Island Medical Society. The paper will be considered for publication in the *Rhode Island Medical Journal*, subject to review by the Editorial Board.

PRESIDENT'S PAGE



The Business of Medicine

Physicians of Rhode Island, and indeed of the entire United States, are rapidly transferring their attention from the *practice of medicine* to the *business of medicine*. No longer is the major topic of discussion an interesting medical case or a difficult diagnostic dilemma — rather, it has become the increasing costs of insurance, problems with reimbursement, competitive practice modes, and the ever-mounting inroads by non-physician health care providers who demand their "share" of the third-party dollar.

What are we to do? Obviously, there has to be a serious change in the physician's posture and the medical society's management of the issues. Strategies must change. We will have to adopt the methods of the business world. Research and development, marketing, political involvement, public opinion surveys, exposure through the press, radio and TV, and all the tools of American business must be evaluated and implemented.

It is clear that this approach will be expensive. Physicians in Florida have contributed \$500 each (in addition to regular dues) to place the medical liability problem before that state's residents in an election referendum to be held in November. Physicians in Texas spent \$2,000 each over a



Paul J. M. Healey, MD

period of three years to conduct the business of medicine.

If we are to learn from our past successes, and there have been painfully few, we cannot afford to do less. ■

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H.M.S.S.



COMMENTARY

Maybe You Can Strike Back

Thomas D. Gidley, LLB

The proliferation of seemingly groundless malpractice suits in recent years has prompted many physicians to ask, "Can I strike back by suing the plaintiff or his attorney?" Because the Rhode Island Supreme Court has not ruled specifically on the issue of countersuits by physicians, the answer to this question has not been clear. However, a recent decision of the Rhode Island Supreme Court, *Salvadore v Major Electric & Supply, Inc.*,¹ which did not involve a physician, indicates that the answer may be affirmative for physicians asking about countersuits.

In the *Salvadore* case, the plaintiff alleged malicious prosecution and civil conspiracy stemming from the filing of four civil suits against him, three of which were terminated in his favor. The defendants in the countersuit included the four parties who had sued *Salvadore* and their attorneys. In an amended complaint, the plaintiff claimed that the lawyers had "acted in concert" with their clients in bringing the 'wholly baseless' civil actions" against him. The Superior Court granted a summary judgment for the defendants, and *Salvadore* appealed the ruling.

The Rhode Island Supreme Court reversed the decision, saying:

As we read the amended complaint, we conclude that it was legally sufficient to withstand a motion to dismiss under Rule 12(b)(6). The plaintiff alleged that each prior proceeding was instituted maliciously and without probable cause and that three of the prior proceedings resulted in judgments, not settlements, in his favor.²

As this language makes clear, a countersuit by a defendant in a civil case will succeed if the case is not settled and is terminated by the court in favor of the defendant, and if the defendant, acting as a plaintiff in a countersuit, can prove that the orig-

inal civil suit "was instituted maliciously and without probable cause." Although the court did not specifically deal with countersuits by physicians, the implication of *Salvadore* is clear. The plaintiff who sues a physician in a malpractice case maliciously and without probable cause is vulnerable to a countersuit if the physician wins the malpractice case.

The status of the plaintiff's lawyer in a baseless malpractice suit is not made clear by *Salvadore*. The lawyer/defendants in the *Salvadore* countersuit argued before the Rhode Island Supreme Court that they could not be sued for malicious prosecution because they were merely agents acting for the disclosed principals, their clients. Because the lawyers had not raised this issue in the Superior Court, however, the Rhode Island Supreme Court would not consider it. As a result, the problem remains unresolved.

The *Salvadore* case should be seen as a warning to plaintiffs who would institute baseless malpractice suits. While the Supreme Court ruling does not mean that *Salvadore* automatically will win the countersuit, it does provide him with the opportunity to try to prove to a jury that he was harmed by the institution of groundless civil suits against him. Although the court expressly refrained from deciding the status of the lawyer defendants in the *Salvadore* case, lawyers who are asked to file obviously weak civil suits on behalf of their clients should be aware that countersuits against them have not been ruled to be beyond the pale in Rhode Island. There is thus hope for physicians who are sued in frivolous malpractice cases. If the physician refuses to permit a settlement and has the patience and fortitude to see the suit through to victory, the *Salvadore* case should provide a strong legal basis for a countersuit.

References

¹ *Salvadore v Major Electric & Supply, Inc.*, 469 A 2d 353 (Nov 9, 1983).

² *Salvadore v Major Electric & Supply, Inc.*, 469 A 2d 353ab 357.

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Professional Liability: The Crisis of the 1980s

Tort Reform and Consumer-Purchased "Maloccurrence" Insurance Offer the Most Promise

Barry M. Manuel, MD

Although many problems currently face physicians, none has a greater potential to harm the individual doctor than does professional liability.

The Crisis of the 1970s

While the word "malpractice" has always conjured up negative feelings among physicians, it was not until 1974-1975 that it began to affect medical practice in a significant way. At that time, a crisis of availability of professional liability insurance occurred. Although a serious increase in the frequency and severity of claims had actually started earlier in the decade, this disturbing new trend was not recognized by insurance actuaries until 1974. The result was a sudden and severe upward adjustment of rates and, in many cases, the termination of the product line by insurance companies. Nationally, the number of companies offering professional liability insurance decreased from 39 to eight. When insurance was available, the premiums often were prohibitively expensive.

Because of this situation, more than 300 statutes were passed by state legislatures throughout the country. Some of the common features of this legislation included: establishment of joint underwriting associations in 35 states to guarantee availability of insurance; establishment of screening or arbitration panels to eliminate non-meritorious claims; elimination of *ad damnum* clauses; reduction of statutes of limitations; limitation of physician liability ("capping"); limitation of legal fees; creation of study commissions; improvement of tort laws; development of self-insurance plans (physician mutual com-

panies) and state insurance funds; and implementation of collateral source rules.

While these legislative changes have provided some relief, it has proved to be temporary. The National Association of Insurance Commissioners, in a study covering the period July 1975 through December 1978, found a significant increase in the frequency and severity of awards. The average award increased 70 per cent and the cost of defending malpractice suits rose by 73 per cent. The average indemnity for very serious but non-fatal injuries increased from \$213,000 to \$349,000. Awards of \$1 million or greater more than quadrupled.¹ The latest figures available from Jury Verdict Research, Inc indicate that this trend is continuing at an alarming rate, with the average award for serious but nonfatal injuries climbing to \$840,396.²

Some of the more obvious reasons for this crisis are readily apparent. Defense attorneys and insurance companies are beginning to question the effectiveness of malpractice screening panels. These panels have been found to be unconstitutional in Florida, Illinois, and Missouri. The legislation authorizing their activities has been repealed in Nevada, North Dakota, and Rhode Island, primarily because the review was thought to undermine the right of judicial access. More claims are going to trial, and court cases are usually more expensive to settle.

Lawyers have discovered the fertile field of birth defects and the enormous awards associated with them. In cases of defective births, there is an increasing tendency for the courts to assign liability to obstetricians. The awards stemming from these cases are intended to provide lifetime compensation for the injured infant. Moreover, there is increased publicity concerning large settlements.

Barry M. Manuel, MD, Associate Dean, Boston University School of Medicine, Boston, Massachusetts.

There are larger assessments of punitive damages. Physician-instigated countersuits have been overturned by many state superior courts, and the United States Supreme Court has refused to adjudicate any of the appeals.

Attorneys are becoming more sophisticated and specialized. As an example, a neurosurgeon who completed legal training now specializes as a plaintiffs' attorney in children who have suffered brain damage at birth. In addition, professional plaintiffs' physicians have become more numerous and more effective.

Magnitude of the Problem

To understand the magnitude of the problem, we must determine whether all cases of malpractice are being litigated.

The California Medical Association performed a medical insurance feasibility study in which 20,864 patient charts from 23 representative hospitals in California were surveyed.³ Some 970 potentially compensable events were discovered, or 4.65 per cent of the total sample. Of these 970 cases, 9.7 per cent resulted in death and 3.8 per cent were associated with permanent functional disabilities. The statistical extrapolation of occurrences from the sample to the statewide hospitalized population produced sizable results as there were 140,000 cases of potentially compensable events.

The study revealed, however, that legal action was rarely instigated and then apparently on a pure chance basis. This would certainly seem to indicate that a great reservoir for future suits exists. To confirm the gravity of the current trend, the *Medical Liability Monitor* recently noted:

A. M. Best Company said that medical malpractice insurance is in serious trouble once again. The adequacy of rates and underwriting requirements of specialty malpractice insurance companies that were begun during the 1970s are now being evaluated, and the outlook is bleak. The combined loss and expense ratio has risen by double digit amounts in each of the last five years. In 1982, the underwriting loss reached nearly \$600 million, compared with a 1977 profit of \$60 million. The pure loss ratio in 1982 was 151.6 per cent.⁴

Fundamental Problems of the Present System

The determination of professional liability does not belong in the courts for several reasons. First, physicians are not tried by juries of their peers. Despite good intentions, most jurors understand little about the practice of medicine and cannot comprehend the complex issues involved in professional liability. Moreover, because juries tend to be vulnerable emotionally to severely injured plaintiffs, their objectivity may be impaired.

Second, there is a fine line between professional liability and "maloccurrence" which even trained experts have difficulty distinguishing. Third, due to prolonged litigation, delays in compensation can cause unnecessary hardship to the injured plaintiff. Fourth, the adversarial system causes substantial harm to physicians, their families, their reputations, and their practices. This damage rarely is reversible even in the case of full exoneration by the courts. Fifth, the costs of the present system are excessive. Administrative and legal expenses account for 82 per cent of all professional-liability premiums, and only 18 per cent of the premium dollar is awarded to injured patients.

Finally, because of the current litigious climate, physicians are being forced to practice medicine more defensively. It has been estimated that the costs of defensive medicine are responsible for approximately 30 per cent of the total costs of health care in the United States. In addition, the quality of medical care can be affected when physicians do not perform a procedure or test because of the fear of litigation, even though the patient might benefit. Even more disturbing is the prospect that specialists may refuse to treat complicated or high risk cases, again with an adverse effect on patient care.

Solutions

Because the legislation initiated during the past ten years has not moderated the malpractice crisis, many other solutions have been proposed. The following four suggestions are among those most frequently mentioned:

Medical Captive Carriers: There currently are 30 physician-controlled liability insurance companies operating in the United States. Although they satisfy a demonstrated need by insuring approximately 110,000 physicians, their fiscal viability is not assured. As the oldest captive carrier only dates from 1975, these companies generally lack the necessary rate experience. The largest of the captive carriers is the Medical Liability Mutual Insurance Company of New York, which has assets of more than \$1 billion. Its recently-filed rate requests have been sharply curtailed by the state insurance commissioner, and questions have been raised concerning the adequacy of its reserves. Professional liability is not an insurance problem but a tort problem. While the physician-controlled liability companies have offered temporary relief, they cannot provide long term solutions.

Lack of Insurance Coverage: Known as "going bare," this usually involves a decision by the physician not to purchase malpractice coverage. It is a terrible choice for both physicians and the public. Although some physicians have attempted to protect their accumulated assets by transferring ownership to other family members, it should be noted that the transfer may be voided by the court if it was arranged primarily to avoid the consequences of a pending or anticipated liability judgment. Moreover, "going bare" is not fair to the patient in those cases where true liability is involved.

Higher Premiums: Professional liability premiums already are reaching levels where physicians and society can no longer afford them. Some high risk specialists currently are paying more than \$60,000 a year for insurance coverage. If pending rate requests are approved, this figure may well escalate to more than \$90,000 annually. Who will pay these costs: physicians, patients, employers, or society? It is obvious that higher premiums provide only a temporary solution to a crisis situation.

Tort Reform and "Maloccurrence" Insurance: It is likely that reform of the tort system, in conjunction with the development of "maloccurrence" insurance, may offer the only permanent solution to the crisis.

Two major components of this approach have been suggested. First, we must remove the existing adversarial relationship between physicians and patients by eliminating the fault-finding aspects of most malpractice actions and transferring the entire process outside the judicial system. This could be accomplished in one of two ways: 1) worker's compensation plans. Under this approach, malpractice claims would be processed in much the same manner as those now filed by employees for work-related injuries. This method of resolving malpractice claims apparently has worked well in Sweden for the past eight years, and there is ample precedent for its utilization in this country as a solution for the injured worker; and 2) "maloccurrence" compensation. A list of compensable "maloccurrences" and their awards could be developed by a panel of such experts as physicians, economists, accountants, rehabilitation counselors, and social workers. When an injury occurred, the attending physician would file a "maloccurrence" form and the patient would receive the listed allowance. Although patients would be free to reject the award and seek judicial relief, it is likely that the number of court actions would be small. The long

delays of most judicial procedures and the danger of losing the case altogether should encourage most injured patients to accept the compensation allowance.

The second major aspect of this approach involves "spreading the risk." If society wishes to be compensated for "maloccurrences," the premium should be allocated among the population at risk, ie, patients. The premium would be a fraction of what physicians now pay for professional liability coverage. Moreover, since implementation of either an "injured patients' plan" or a compensation schedule would reduce the existing administrative and legal costs, a larger percentage of the premium would be spent on injured patients. Physicians still would need to purchase professional liability insurance for those cases where they were impaired by substance abuse or illness, or where they were practicing outside their area of expertise.

Prognosis without Tort Reform

The professional liability crisis of 1975-1976 was primarily one of insurance availability. The crisis of the 1980s will be one of cost and will prove to be far more damaging to physicians and more disruptive to the health care delivery system. There will be a further reduction in commercial companies offering professional liability insurance, and those remaining in the marketplace will sell policies at a prohibitive cost. Many of the physician-controlled mutual companies may not have the resources to honor their commitments. Physicians who have paid their premiums will find that there are insufficient reserves to cover their claims, and their personal assets may well be attached. Faced with this crisis, physicians will initiate "work actions" similar to that which occurred in Florida. At this point, the government will be forced to intervene, most likely in a way that is not beneficial to either physicians or their patients.

Conclusion

Professional liability is one of the most severe problems facing the health care delivery system in this decade. The increasing frequency of litigation and the size of awards have triggered substantial increases in premiums for professional liability coverage. As a result of the malpractice crisis, physicians are forced to practice medicine more defensively, often at a significant societal and personal cost. The present system is inefficient and inequitable, and does not benefit the

injured patients it was intended to help.

While several potential solutions have been advocated, tort reform in conjunction with consumer-purchased "maloccurrence" insurance appears to be the most promising. While obtaining the necessary legislation will not be easy, the task can be accomplished with the support of a growing constituency of those affected by the current tort system, including architects, engineers, and manufacturers.

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- ⁴ Medical Liability Monitor. Mar 23, 1983, vol 8, no 3.

80 East Concord Street
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HAVE YOU HEARD? . . .

A new series of ultraviolet water sterilizers designed to eliminate microorganisms without the use of heat or chemicals has been introduced by Beckman Instruments, Inc. Intended for use with potable, non-potable, and high purity water, the Beckman Type UVS Water Sterilizers destroy bacteria, viruses, algae, spores, and yeast by exposure to ultraviolet light at a germicidal wavelength. The new sterilizers, according to company officials, operate from standard electrical current and have no moving parts.

The Sarns 7400 Pulsatile Blood Pump,[®] designed for use during open-heart surgery, has been selected by the National Society of Professional Engineers as one of three winners in its first New Product Award competition. Sarns, Inc is a subsidiary of the 3M Company Surgical Products Division.

Developed in 1982, the machine delivers two forms of pulsating blood flow to stimulate cardiac action as well as the continuous flow of conven-

tional blood pumps. Through an internally-triggered pulsatile mode, the pump generates a pulse rate controlled by the perfusionist. According to clinical studies, internally-triggered pulsatile perfusion provides better organ, cerebral, and peripheral perfusion than does continuous flow. Metabolic benefits also have been reported, including significant reduction in acidosis, lactate formation, and creatinine release. During its second pulsatile mode, the blood pump is triggered by the patient's R-wave signal. This method may be utilized at the end of the pump cycle to reduce cardiac stress while a normal heart beat is reestablished.

A new miniature scanhead, intended for use in neurological, vascular, and general surgery has been introduced by Advanced Technology Laboratories, Inc. The ACCESS[®] B scanhead is designed specifically for use with the company's surgical ultrasound system. Weighing only 680 g, it incorporates three transducers with differing frequencies to optimize image quality at multiple scanning depths. The scanhead requires a contact area of 1.45 cm and may be utilized readily in small operative sites. It comes with a flexible connecting cable. Advanced Technology Laboratories, Inc, a division of the Squibb Company, is a supplier of ultrasound and digital fluorographic systems.

A study of marijuana use among 1,325 young adults published in the February 1984 issue of the *Archives of General Psychiatry* suggests that users are characterized by higher use of other psychoactive substances, lower participation in conventional adult roles, and histories of psychiatric hospitalization. Researchers at the Columbia University School of Public Health report that marijuana use reaches a peak between the ages of 20 and 22 years and declines after the age of 25 years.

The Health Care Financing Administration (HCFA) is seeking ways of restricting Medicare reimbursement for enteral and parenteral nutrition for nursing home patients because of alleged abuses by physicians. Payment for such nutrition currently varies widely because of ambiguous HCFA guidelines. Payments are presently made under Part A or Part B for the feedings as part of
(continued on page 289)

Professional Liability

The Majority of Patients Will Not Sue Physicians Who Show Compassion, Sensitivity, and Courtesy

Mark S. Mandell, JD

All of us are required to exercise reasonable care for the safety of others. Under the law, we are liable for any harm resulting from negligence, or the failure to exercise such care. Negligence by a professional person is called malpractice. Within the context of medical care delivery, the failure to demonstrate reasonable care is operationally defined as a deviation from accepted or standard medical practice, also known as the "standard of care."

To assert successfully a claim for medical negligence, a plaintiff must prove that a relationship existed between the physician and patient, that the physician violated the standard of care by failing to provide the proper treatment and care to the patient, and that the patient sustained an injury as a result of the deviation from the standard of care by the physician.

The Physician-Patient Relationship

The physician-patient relationship is based on an implied contract which occurs when the patient seeks treatment and the physician accepts the person as a patient. In the absence of statutory law to the contrary, physicians are not required to accept as patients all who seek their services.

The existence of a physician-patient relationship is a question of fact, and generally is not disputed in medical negligence cases. The principal consideration involves a determination of whether the patient entrusted his treatment to a physician who accepted the case. Once established, the relationship exists until it is terminated by mutual consent, by the patient unilaterally, or until the services of the physician are no longer required. In the absence of a specific agreement, there is an implied requirement that physicians will provide care as long as medical attention is necessary.

Mark S. Mandell, JD, Partner, Mandell, Goodman & Schwartz, Ltd., Providence, Rhode Island.

Standards of Care

The professional standard of care requires the physician to possess and exercise the degree of knowledge, care, and skill that other competent physicians ordinarily would demonstrate under the same or similar circumstances. Physicians should act in a way that is acceptable to their professional peers or to the reasonably prudent physician. The failure to do so constitutes malpractice. For the most part, the profession determines its own standard of care.

There are certain refinements and exceptions to this general rule. First, the courts recognize that disagreement often exists within the profession as to the appropriate procedure or treatment. According to the "acceptable minority" rule, there is no negligence or deviation from the standard of care if physicians reasonably choose one of several recognized courses of action. The important qualifying requirement is that the choice be medically reasonable under the circumstances. Similarly, the "error in judgment" rule provides that physicians who reasonably exercise their best judgment are not negligent, even if the judgment turns out to be erroneous and leads to a bad result, as long as it falls within the range of valid differences of opinion among competent physicians.

An additional problem is that physicians have varying levels of training and skill. A specialist in a particular field of medicine is held to a higher standard of care than is a general practitioner. Specifically, a specialist must exercise the same degree of care and skill as would be exercised by other competent practitioners of the same specialty. While the courts do not impose a higher legal duty on specialists than on general practitioners, specialists are required to be more skillful than nonspecialists in discharging their duties.

During the nineteenth and early twentieth centuries, the "locality rule" limited the application of the standard of care to the geographic location of the defendant physician. As the result of im-

proved communication systems and greater uniformity of education and practice, a strict interpretation of the locality rule has generally been abrogated, initially in favor of a "same or similar locality" frame of reference, and most recently following a uniform national standard of care.

Expert Testimony

Because the relevant legal standard of care is established by the medical profession, a jury ordinarily may not find a defendant physician to be negligent unless another physician tells them that an act of medical negligence took place. Consequently, to win a medical malpractice case, the plaintiff generally must introduce the testimony of a physician practicing the same specialty as the defendant. The expert witness must present testimony on the relevant standard of care required under the circumstances and state that the acts or omissions of the defendant physician deviated from that standard. It is this violation of the standard of care that actually constitutes medical malpractice.

Injury and Legal Causation

In addition to demonstrating a violation of the standard of care, the claimant also must prove that he suffered an injury resulting from negligence by the defendant physician. The expert witness must testify that it is probable, ie, reasonably medically certain, that the injury was caused by a deviation from the standard of care.

In this connection, a legal doctrine occasionally cited in medical malpractice cases is *res ipsa loquitur*, which means "the thing speaks for itself." This theory is used when the plaintiff has no direct proof of a specific negligent act, but can establish that the injuries sustained do not ordinarily occur in the absence of negligence. As an example, the plaintiff may have suffered an ulnar nerve injury during surgery on some other part of the body. Although the plaintiff may be unable to establish what actually happened in the operating room, he can introduce expert testimony that such an injury does not ordinarily occur unless the surgeon or anesthesiologist is negligent in positioning the patient's arm.

Breach of Guarantee of a Particular Result

On occasion, a physician may guarantee unwisely that treatment will produce a particular result. Under the law, such a guarantee is regarded as a contract and, if the promised result does not materialize, the patient may recover for what is

essentially a breach of contract. To be liable for an actionable violation, physicians must go beyond offering mere therapeutic reassurances by making a specific and precise statement that a particular outcome is guaranteed or certain.

Informed Consent

The unstated foundation of the doctrine of informed consent is the basic inequality inherent in the physician-patient relationship. This inequality stems both from the superior knowledge of medicine held by the physician and from the frequently urgent need for care by a patient who lacks any real bargaining power. Each individual patient needs medical services much more than the doctor needs that particular patient. In effect, this inequity creates a fiduciary relationship between the physician and the patient. As a trustee, the physician must satisfy a relatively stringent obligation to provide enough information to patients to allow them to make informed, intelligent, and voluntary choices as to the appropriate course of treatment.

The doctrine of informed consent imposes a duty upon physicians which is completely separate and distinct from their responsibilities to diagnose and treat illness skillfully. The liability for failure to obtain informed consent does not require any negligence by the physician either in the choice of treatment or in its administration. Instead, liability is based upon the fact that the patient was not informed of certain inherent risks of the procedure, that one of those risks actually materialized, and that consent probably would have been withheld if the patient had been fully informed.

Disclosure Requirements

The following information must be disclosed when physicians obtain informed consent from their patients: the diagnosis, the nature and purpose of the proposed treatment, the risks and consequences of its administration, the probability of its success, the prognosis if the proposed course is not followed, and feasible treatment alternatives.

Under certain circumstances, physicians may safely fail to disclose information to their patients. These exceptions to the informed consent disclosure requirements include:

Emergencies: In an emergency situation where disclosure is impractical, the need for immediate treatment overrides the concern for consent.

Therapeutic Privilege: In certain situations, the complete disclosure of information to patients

may be detrimental to their health. The purpose of this exception is not to reintroduce the paternalistic concept that physicians should determine the appropriate treatment unilaterally and accordingly limit disclosure. Rather, it is intended to cover those cases where full disclosure would cause such a state of emotional agitation in patients as to preclude rational decisions, impede treatment, or actually result in psychological harm. If possible, a psychological consultation should be obtained. The courts appear to have adopted a professional standard concerning the reasonableness of the defendant's belief that disclosure would be harmful.

Other exceptions: There is no need to disclose risks which are commonly known or reasonably presumed to be known by the patient. Similarly, it is not necessary to disclose a risk that was unknown at the time. While information may be withheld if the patient prefers not to be told of the risks, prudence dictates that physicians obtain signed waivers from these patients.

It should be noted that patients are not automatically entitled to recover damages simply by proving that disclosure did not take place. The plaintiff also must demonstrate that the injury in question was caused by a materialization of risks about which a warning should have been given. Moreover, the injury suffered must be measurably worse than what the patient's condition would have been without treatment. Finally, it must be established that the patient would have acted differently if the risks were disclosed and that the injury actually resulted from the therapy in question.

Why Do Patients Sue?

Patients generally file malpractice suits against their physicians for one of two reasons. The first, lack of civility, is almost entirely avoidable. The second, catastrophic results, is not.

Rudeness is the triggering complaint responsible for most malpractice litigation. During their initial interviews with legal counsel, potential plaintiffs are most likely to complain of being treated without any sensitivity, compassion, or understanding, or of being regarded as "just one of a series of numbers."

Condescension is viewed by patients as a complete abuse of their trust in the physician. It is the single greatest cause of malpractice litigation. If physicians abuse the power stemming from this trust, they cannot exercise their fundamental responsibilities to patients. Patient responsiveness diminishes in direct proportion to the degree of

insult, insensitivity, and indifference.

Confronted with such rudeness, patients with comparatively minimal injuries may institute malpractice actions. Legal redress will be sought because these patients feel slighted, insulted, hurt, and abandoned, and not because they are inherently litigious.

The solution is simple. If physicians were to address their immense creative and clinical talents to demonstrating more compassion and courtesy toward patients, the number of suits would decrease dramatically. Physicians must take the necessary time with patients to explain their present condition, the treatment modes available, and the chances of success. To patients, the prognosis is the most important consideration. A reasonable and honest attempt to communicate in a caring, sensitive way strikes a responsive chord in most persons. A great majority of patients simply will not sue physicians who have shown compassion, sensitivity, and courtesy.

The second reason for malpractice actions may prevail regardless of the presence of rapport. Catastrophic medical or surgical results often cause litigation even when patients truly admire their doctors. The mother of a profoundly brain-damaged child will sue her obstetrician for the prohibitive costs of providing her child with constant nursing care, even though a healthy relationship has developed. Despite friendship, a sterile patient will sue because she is unable to conceive. Even when the gynecologist has been sensitive, caring, and conscientious, the performance of a radical mastectomy may lead to considerations of legal action.

Faced with catastrophic results, physicians should immediately consult with the most qualified specialists available in the appropriate field. It may well be possible to limit the adverse results. A consultation also helps determine the cause of the complication. If the catastrophe was not caused by negligence, a patient will be more likely to exonerate the physician and avoid litigation if another plausible explanation is offered.

Every effort should be made to obtain the best possible treatment for the complication. It is essential to monitor the care closely and maintain close contact with the physicians responsible for the continuing treatment. After the complication becomes apparent, full disclosure should be made to the patients and their families and the original physician should stay in touch with the family. Patients who feel supported by their physicians during their hour of need are much less likely to sue. ■



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The Joint Underwriting Association: Status Report and Reflections

JUA Experience Indicates that Legislative Reform Is Still Imperative

Kenneth E. Liffmann, MD, FACS

Effective June 16, 1975, the Rhode Island Department of Business Regulation adopted Emergency Regulation XXI which established the Medical Malpractice Joint Underwriting Association of Rhode Island (JUA). Subsequently, the General Assembly approved legislation which authorized the Department of Business Regulation to promulgate regulations relating to medical malpractice insurance and validating Emergency Regulation XXI. The intent of these two sequential actions was to provide a continuing stable source of medical malpractice insurance and incidental coverage for all providers of health care in Rhode Island. This objective has been achieved.

Joint Underwriting Association

The JUA is a hybrid. It is not an insurance company in a classical sense, but rather an instrumentality of the State of Rhode Island under the control of the Director of Business Regulation. The Association is governed by a board of fifteen directors, eight of whom represent casualty insurance companies. The remaining seven directors are appointed by the Director of Business Regulation: five are medical doctors, one is an osteopathic physician, and one represents the Hospital Association of Rhode Island.

A Stabilization Reserve Fund is administered by the Director of Business Regulation or his

deputy, with the guidance of a two-member advisory board appointed by the director.

All physician policies issued since inception have been on a "claims occurrence" basis, providing coverage for the policyholder for claims incurred during the policy year regardless of when the claims are reported to the JUA. The Association is authorized to issue policies with limits not to exceed \$1,000,000 for each incident under one policy and \$3,000,000 for all incidents under one policy in any one year.

The Board of Directors meets approximately six times annually, and various subcommittees meet with underwriters, investment advisors, legal counsel, actuaries, and other purveyors as necessary. The JUA does not retain any employees, but contracts for four defined functions on a competitive bidding basis: carrier and claims handling, investment service and custodial function, actuarial services and preparation of rate filing, and risk management services. Corporate and specialized legal counsel are retained on a continuing basis.

Premiums are collected and invested in high-grade government, government agency, and corporate bonds. The income from these investments is applied annually to reduce premium charges. This policy is unique to an association of this type, since there are no stockholders or policyholders who receive dividends or return of premiums.

Claims losses, allocated loss adjustment expense, agent commissions, and fees for the contracted services are charged to the main underwriting fund of the JUA. If this fund should become depleted, the Stabilization Reserve Fund would be utilized. If the resources of both the Underwriting Fund and the Stabilization Reserve Fund become exhausted, the Director of Business Regulation may authorize the casualty insur-

Kenneth E. Liffmann, MD, FACS, currently serves as Chairman, Board of Directors, Medical Malpractice Joint Underwriting Association of Rhode Island. He is a surgeon at Rhode Island Hospital, Providence, and Clinical Assistant Professor of Surgery, Brown University Program in Medicine. Doctor Liffmann also is treasurer of the Rhode Island Medical Society.

ance companies to apply a surcharge on future policies (eg, home owners, marine, and fine arts) issued in this jurisdiction or deduct their share of the deficit from past or future Rhode Island taxes. In this manner the Association is assured of a stable source of funding for its continuing operations. There is an assigned risk pool of approximately 300 casualty insurers in Rhode Island. For this reason, representatives from the insurance industry hold the majority on the JUA Board.

In the continuing discharge of business since the establishment of the JUA, the cooperation and consolidation of interests to make this plan work have been exemplary. The Department of Business Regulation, members of the insurance industry, and representatives of the health care providers have maintained harmonious relations and potentially conflicting interests or positions have been reconciled to advance the community interest.

This conclusively demonstrates the presence of a viable vehicle to write medical malpractice insurance, both from the regulatory and organizational structure. The Association currently insures approximately 1,750 physicians, surgeons, and other health care providers, as well as eight hospitals. In recent months, five hospitals have obtained their malpractice insurance from the private sector, and this is the first significant return to the marketplace by the insurance industry in Rhode Island for this line of business. It is notable that a mass marketing for physician accounts has not materialized. The hospital policies apparently have been written as part of a comprehensive insurance package for these institutions.

The external factors which directly influence the malpractice problem in Rhode Island have been complex and are directly intertwined with the operation of the JUA. On April 14, 1983, the Rhode Island Supreme Court finally issued a ruling to the effect that malpractice panels or screening mechanisms are unconstitutional. The prior organization did not recommend their continuation, since the system was cumbersome, caused delays, and prolonged disputes. While pretrial screening was an interesting idea, it simply did not work in Rhode Island and finally was found to be unconstitutional. As a result, malpractice suits accumulated in the court system. As of February 1, 1984 there were 399 malpractice claims in litigation against physicians. Moreover, the problem is compounded by prejudgment in-

terest of 12 per cent annually calculated from the date of the alleged injury.

JUA Experience

Between the inception of the JUA in 1975 and February 1 of this year, there have been 907 suits directed against physicians. Of these, 399 remain open and 508 have been closed. In addition, there have been 554 incident claims (ie, non-suits); 116 of these remain open and 438 have been closed. The total number of physician claims since inception is 1,461.

The disposition of the 508 closed suit claims is as follows: settled before trial (289); dismissed by plaintiff's attorney or by court order (180); tried and won (11); and other coverage applied (27). One case which was tried and lost is still open on appeal. The disposition of closed incident claims is as follows: settled (87); closed without payment (314); and other coverage applied (10). During the period under consideration, the total paid losses were \$13,310,197 and allocated loss adjustment expense totaled \$1,134,267. The largest total dollar settlements have been in obstetrics-gynecology, followed by general surgery and orthopedic surgery.

There have been 46 plaintiff attorney firms handling these claims versus seven defense firms. It can be seen that the bar in this jurisdiction has been industrious, and that there is considerable specialization among the attorneys in this area of litigation.

The severity of both court-ordered settlements and those cases settled out of court has increased. As an example, the average paid loss at 36 months for a 1975 claim was \$5,830 while the average 1980 claim settled after three years was \$124,699. These adverse developments are reflected in the current high premiums. While the megacrisis may have passed, the cost trends are still of "normal" crisis proportions, despite the fact that the rate of increase in claims frequency has stabilized at four or five per cent annually. It is the escalating size of awards and settlements that presents the most threatening element.

The Need for Reform

An important palliative for this disastrous prospect may be legislation to limit the size of malpractice awards. There are some compelling arguments in favor of limits. First, the cost to patients would be moderated. Second, as insurance rates increase, insurance becomes less and less a useful economic protection. The tendency of physicians and hospitals to forego insurance

and "take the risk" will grow. Third, the growth of insurance has distorted the operation of traditional tort practices. The large settlements currently seen certainly are partially attributable to high insurance coverage. There is a point at which insurance companies cannot cover risks that threaten to expand without limit.

This type of reasoning has intellectual appeal in 1984, just as the establishment of malpractice panels had in 1975. A limitation on the size of awards, however, may impair the rights of the public to legal redress. In view of the 1983 Rhode Island Supreme Court decision, it has become clear that legislative reform specifically intended to address the medical malpractice situation would be ill-advised. Broader legislation dealing with medical malpractice, legal malpractice, product liability, and other liability issues stands a better chance of being successfully enacted and upheld on challenge.

A recent paper by Hilfiker presents an introspective, psychological analysis of physician mistakes as well as the societal view: "Everyone, of course," he states, "makes mistakes, and no one enjoys the consequences. But the potential consequences of our medical mistakes are so overwhelming that it is almost impossible for practicing physicians to deal with their errors in a psychologically healthy fashion. Most people —

doctors and patients alike — harbor deep within themselves the expectation that the physician will be perfect. No one seems prepared to accept the simple fact of life that physicians, like anyone else, will make mistakes."

Hilfiker continues, "If the profession has no room for its mistakes, society seems to have even more rigid expectations of its physicians. The malpractice situation in our country is symptomatic of this attitude. In what other profession are practitioners regularly sued for hundreds of thousands of dollars because of a misjudgment?"

"Even the word 'malpractice' carries the implication that one has done something more than make a natural mistake; it connotes guilt and sinfulness."

It is within this context of social expectations that the Joint Underwriting Association continues to operate.

Acknowledgment

The preparation of the summary statistical data of the Joint Underwriting Association by William E. Egan and Bruce Campbell of staff is acknowledged with appreciation.

Reference

Hilfiker D: Sounding board. Facing our mistakes. *N Eng J Med* 310(2):118-122, 1984.

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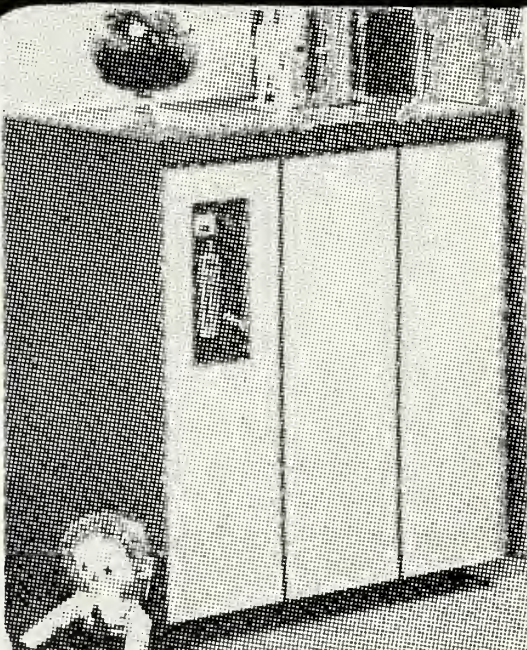
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RADIOGRAPHIC CASE OF THE MONTH

Michael J. Ryvicker, MD
Sanford L. Schatz, MD
Howard R. Cohen, MD
Allan M. Deutsch, MD

Department of Radiology
The Miriam Hospital
Providence, Rhode Island



Fig 1

History:

This 36-year-old man was admitted to the hospital because of cramping abdominal pain and bloody diarrhea.



Fig 2

For discussion, see next page.

Radiographic Findings and Discussion

Preliminary radiographs of the abdomen reveal air in the transverse colon. This air column is indented by multiple "thumb-prints," indicating a thickened or edematous mucosa. This may be seen in ulcerative colitis, in the subacute stage, due to inflammatory pseudo-polyps, as well as in granulomatous colitis, due to transverse and lon-

gitudinal ulcerations producing a nodular "cobblestone" pattern. Ischemic colitis may also present "thumb-prints," due to submucosal edema or bleeding.

Barium is seen in the terminal ileum and colon, via an antegrade study. This examination reveals a patulous terminal ileum, as seen in ulcerative colitis with back-wash ileitis. The previously described nodules are now demonstrated against the barium-filled lumen.

Surgical pathology revealed inflammation in the mucosa and submucosa; no granulomas were seen. There was hyperplasia of the mucosa, with broad areas of ulceration and pseudo-polyps. These findings are characteristic of chronic ulcerative colitis.

Reference

- ¹ Margulis AR, Burhenne HJ: Alimentary Tract Roentgenology. St. Louis, CV Mosby, 1967, pp 742-783.



Fig 3

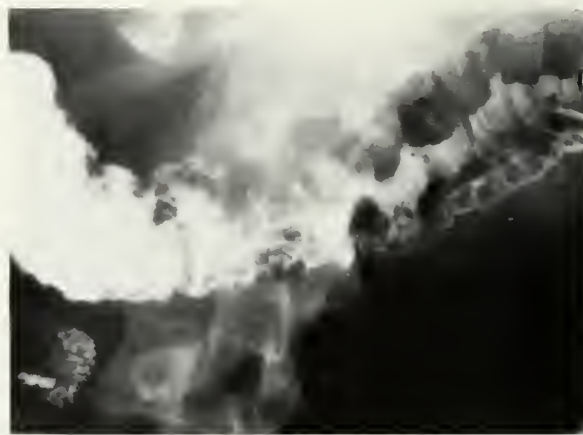


Fig 4

The Miriam Hospital
Providence, Rhode Island 02906

Have You Heard . . .

(continued from page 278)

a category covering "durable medical equipment, prosthesis, and other methods." Because these payments often are higher than for traditional nutritional methods included as part of total room and board expenses, HCFA contends that some physicians may utilize enteral and parenteral methods unnecessarily.


• • •

According to the international accounting and consulting firm of Arthur Young, there will be fewer full service community hospitals and more small neighborhood healthcare facilities specializing in "routine services." In a keynote address before the Healthcare Management Systems Society of the American Hospital Association, Neal F. Bermas, PhD, National Director of Health Care Productivity Services, said that 1,000 hospitals may well close their doors by 1990 as the result of increased competition, changing government regulations, and intense pressures to reduce expenditures. Filling the void will be the establishment of specialty healthcare centers providing emergency treatment, minor surgery, and maternity services on an outpatient basis. Known as "doc-in-the-boxes," some of these centers will "even lend themselves to franchising opportunities."

More and more hospitals, according to Bermas, are responding to economic pressures by diversifying into profitable activities outside the healthcare field. As examples, he cited a Los Angeles hospital owning a parking lot, a Dallas hospital controlling an insurance company and a construction firm, and a New Mexico facility owning a West Virginia coal mine.

• • •

The Food and Drug Administration (FDA) has approved a chewing gum containing nicotine to help physically-dependent cigarette smokers. Available only by prescription, the new product, Nicorette,[®] does not eliminate the desire for a cigarette, but provides a short-term alternative source of nicotine. FDA officials claim that the gum, which is manufactured by Merrell Dow Pharmaceuticals, is not addictive. Smokers who have a high physical dependence on nicotine are the most likely to benefit. Such persons typically smoke more than 15 cigarettes a day, prefer brands of cigarettes with amounts of nicotine greater than 0.9 mg each, and find that the first



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Use of the gum is contraindicated for pregnant or nursing mothers, persons with certain heart conditions, those with dysfunctions which make chewing difficult, and non-smokers, according to the FDA.

• • •

The standards now used to establish brain death may be too rigid, according to a report in the February 1984 *Archives of Neurology*. Doctor Edward V. Spudis and his colleagues at the Bowman Gray School of Medicine report that, because of strict brain death criteria, many severely-ill patients, who would have been declared dead prior to 1969, have been "zealously maintained on life-support systems waiting for cardiac and renal failure."

While the current standard requires an electroencephalography (EEG) reading of two or less microvolts, the researchers suggest that EEG rhythms hovering in the range of two to four microvolts may be false-positive indications of brain activity. Moreover, they recommend avoiding use of the terms "present" or "absent" brain waves. Instead, physicians should focus on the range of amplitude for any forms which appear to be brain waves. The loss of amplitude, according to Doctor Spudis, should be evaluated in conjunction with radiologic and imaging studies and the results of blood and chemistry studies.

• • •

The Pharmaceutical Division of Mead Johnson & Company recently introduced a new form of Cytosan® (cyclophosphamide) which substantially reduces the preparation time required for the injectable solution. Company officials claim that the technology utilized for the lyophilization (freeze-dry) process represents a "significant breakthrough" in terms of convenience for the patient. In its new form, the product can be totally dissolved and ready for use within 45 seconds, compared to a previous reconstitution time of up to six minutes. First made available by Mead Johnson & Company in 1959, Cytosan® is packaged in parenteral and oral forms and is indicated for the treatment of a broad range of malignancies.

• • •

The "shaken baby syndrome" is a common type of child abuse and may result in serious injuries, according to a study reported in the February

1984 issue of the *Annals of Emergency Medicine*.

Twenty of 1,250 child abuse cases reviewed at the Children's Hospital of Philadelphia met the criteria for the syndrome. Three children, or 15 per cent, died as a result of the abuse. Of the surviving children, 50 per cent developed such significant injuries as blindness, visual and motor impairments, seizures, and developmental delays. While 35 per cent of the victims survived with no apparent permanent injuries, the report suggests that undetected cases of shake injury may be responsible for many cases of mental retardation.

Young children between the ages of one and 15 months are most vulnerable to this form of injury because their weak neck muscles cannot support the size and weight of their heads. Moreover, their thin and fragile central nervous system structure and their brains are less protected than in older children and adults. Infants may be frequent victims because they often cry for no apparent reason, causing feelings of frustration, anger, and inadequacy in their parents.

• • •

The first report of cocaine snorting resulting in intracranial bleeding is noted in the February 1984 issue of *Archives of Neurology*. Doctor Peter J. Lichtenfeld and colleagues at the State University of New York at Stony Brook report two cases of subarachnoid hemorrhage precipitated by cocaine snorting. Damage was identified by computed tomographic scans of the head, and included an aneurysm that required surgery and a large arteriovenous malformation.

• • •

Norwich Eaton has recently developed Vivonex® TEN (Total Enteral Nutrition), a single formula designed to reduce the inventory requirements faced by hospitals stocking more than 40 enteral formulas. Intended for utilization in patients suffering from stress, impaired digestion, or malnutrition and cachexia, Vivonex® TEN may be administered through feeding tubes or orally. It also may be used for bowel preparation prior to diagnostic and surgical procedures and as a transition diet between parenteral and normal oral feeding.

• • •

The DuPont Company recently introduced two medical assay kits to assist clinicians in developing

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appropriate therapeutic management of breast cancer. Designed to be used together, the two methods are intended to detect estrogen and progesterin receptors in the breast tissue. A positive assay would indicate that tumor growth has been influenced by normal female hormones and suggest surgical intervention. Negative results would indicate the utilization of such alternative therapies as chemotherapy.

While the correlation between estrogen and progesterin receptors in breast tumors and hormonal therapy was first reported in 1974, DuPont officials claim that their new product is the first commercially-available standardized method for detecting these receptors.

• • •

Injectable collagen is an "easy-to-use, safe, and effective method" for reducing the visual impact of some facial wrinkles and scars, according to a study reported in the February 1984 issue of *Archives of Otolaryngology*. In a review of results in 300 patients at the University of Southern California School of Medicine, it was found that such age-related facial lines as vertical "frown" furrows and creases around the mouth responded well to collagen treatments. The results with acne scars were variable. Delayed hypersensitivity, the only serious complication reported, developed in 1.3 per cent of the patients who developed such reactions as persistent redness, swelling, and itching.

• • •

The consequences of public fears about the acquired immune deficiency syndrome (AIDS) and blood transfusions pose a more significant threat to public health than the disease itself, according to the American Council on Science and Health (ACSH), an independent research organization. In the January 1984 issue of *ACSH News and Views*, it was noted that the actual danger of contracting AIDS from a blood transfusion is extremely remote. Moreover, last March the voluntary blood banking organizations which collect the majority of blood used in the United States initiated procedures to exclude members of groups at high risk for AIDS from donating blood.

Blood banking organizations have opposed the concept of "directed donations" where blood is donated for a specific patient by family and friends. It has been emphasized that such donations are not necessarily safer, could seriously

(continued on page 294)



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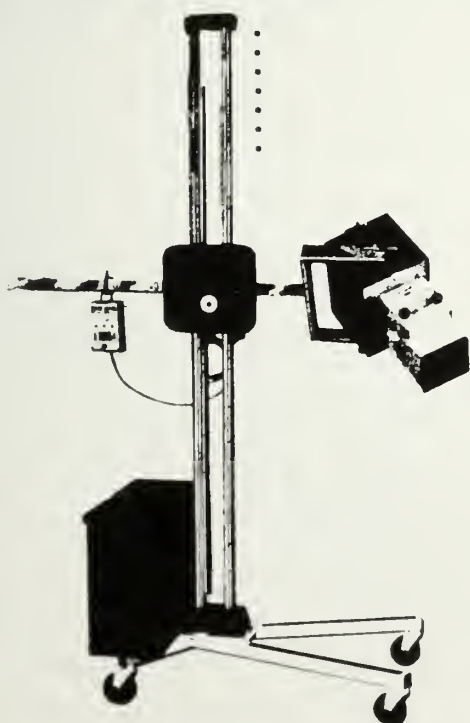
Do You Know an Impaired Physician?

Treatment of physicians for alcohol addiction shows a favorable outcome in 83 per cent of cases, and treatment of physicians for drug addiction has a 95 per cent success rate. More than 70 per cent of the physicians entering treatment return to the active practice of medicine.

The Rhode Island Medical Society Committee on Impaired Physicians, chaired by Dr Herbert Rakatansky, meets monthly. It is a standing committee of the Society charged with "helping physicians whose professional judgments and capabilities are impaired by their difficulties with chemical dependency or other illnesses."

The Committee handles inquiries in *complete confidence*. If you know of a physician who needs an advocate and support in obtaining necessary treatment, please call or write Dr Rakatansky c/o The Committee on Impaired Physicians, Rhode Island Medical Society, 106 Francis Street, Providence 02903 (401/331-3207).

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(continued from page 292)

disrupt the national blood banking system, and create new hazards by requiring additional clerical and administrative steps, thus increasing the potential for fatal errors.

• • •

The American Council on Science and Health recently warned that "skillfully worded, but misleading" vitamin advertisements may induce consumers to buy unnecessary vitamin supplements. The January issue of the organization's newsletter presents details on some specific vitamin advertisements that have been reviewed by the National Advertising Division of the Better Business Bureau because of their potential misrepresentation. The current most popular theme in vitamin advertising is stress and its effects on vitamin requirements. This presents a serious problem as "stress" is not defined consistently, making it difficult to measure the efficacy of vitamin supplements.

• • •

Although cancer is the second leading cause of death in the United States, the incidence of most cancers, excluding carcinoma of the lung, has not increased during the past 40 years. The November-December 1983 issue of the *Dairy Council Digest*, published by the National Dairy Council, reports on several population surveys, experimental animal studies, and *in vitro* tests which relate dietary factors to the pathogenesis of cancer of the breast, large bowel, prostate, and stomach. While the direct impact of diet on carcinogenesis currently remains unclear, the *Digest* notes that several possibilities have been investigated. Among these are the probability that diet may contain carcinogens (eg, aflatoxin), precarcinogens (eg, nitrate), or natural inhibitors (eg, indoles). Indirectly, diet may alter hormone levels, host immune functions, cell membrane permeability, and intestinal flora, which in turn may modulate the growth of tumors. Moreover, excess energy, lipids, and protein are suspected of increasing carcinogenesis, while vitamins A, C, and E and the trace element selenium may stimulate a protective effect. While the *Digest* cautions that "much remains to be learned about the diet-cancer hypothesis," it suggests that a nutritionally-balanced diet and maintenance of a desirable body weight are "the best advice for reducing the risk of cancer and improving overall health."

Information for Authors

Manuscripts: Manuscripts will be accepted for consideration with the understanding that they are original contributions, have never been published or submitted elsewhere, and are submitted only to the *Rhode Island Medical Journal*.

Specifications: Manuscripts must be original typed copy (not all capitals) on 8½x11 inch firm typewriter paper, double-spaced (including the text, case reports, legends, tables, and references) with 1½ inch margins. Carbon copies will not be accepted. Subheadings must be inserted at reasonable intervals to break the typographic monotony of the text. Pages must be numbered consecutively. Italics and boldface print are never used except as subheadings.

Abbreviations: The *Journal* attempts to avoid the use of jargon and abbreviations. All abbreviations, especially of laboratory and diagnostic procedures, must be identified in the text.

Title page: All manuscripts must include a title page which details the following information: (1) a brief title; (2) the name of the author or authors with the highest academic degree (ie, MD, PhD); (3) a concise biographical description for each author which includes specialty, practice location, academic appointments, and primary hospital affiliation; (4) mailing address of principal author; and (5) office telephone number of principal author.

Illustrations: Authors are urged to use the services of professional illustrators and photographers. Drawings and charts should always be done in black ink on white paper. Clear, black and white glossy photographs should be submitted, and such illustrations numbered consecutively and their positions indicated in text. Original magnifications should be noted. Illustrations defaced by handwriting or excessive handling will not be accepted. The figure number, indication of the top, and the name of the author must be attached to the back of each illustration. Legends for illustrations should be typewritten in a single list, with the numbers corresponding to those on photographs and drawings. Recognizable photographs of patients are to be masked and must carry with them written permission for publication.

Special arrangements must be made with the editors for excessive illustrations. Color plates are not acceptable.

Reprints: Because of cost considerations, reprints are not provided routinely to the author(s). Reprints may be ordered separately (100 copies minimum order) and printing costs will be charged to the author(s).

Responsibility: Manuscripts are subject to editorial revisions as deemed necessary by the editors and such modifications as to bring them into conformity with *Journal* style. However, neither the editors, nor the publishers, nor the Rhode Island Medical Society will accept responsibility for statements made or opinions expressed by any contributor in any article or feature published in the pages of the *Journal*.

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References: References should be limited to those citations noted in the text. The references must be typed double-spaced and numbered as they appear consecutively in the text, with their positions clearly indicated in the text. All references must be checked to assure complete accuracy. Each journal reference must include the full name of the author(s); complete title of paper; name of publication; volume number; issue number; first and last page of paper; and date (year, month, and day as indicated). Each book reference must include the full name of author(s), editor(s), or both, with initials; title of book; edition; publisher; location; year of publication, volume (if given); and page number. If the reference is to a chapter within a book, the author of the chapter, if different than the author of the book, and the title of the chapter (if any) must be provided.

It is rarely desirable to include a complete review of the literature in the references. An alphabetized bibliography is to be used only when the listing is of books suggested for supplementary reading.

Before prescribing, see complete prescribing information in SK&F CO. literature or PDR. The following is a brief summary.

*** WARNING**

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Anti-hypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, Dyazide should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on Dyazide when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with Dyazide. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. Dyazide interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with Dyazide but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and Dyazide should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. Dyazide should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

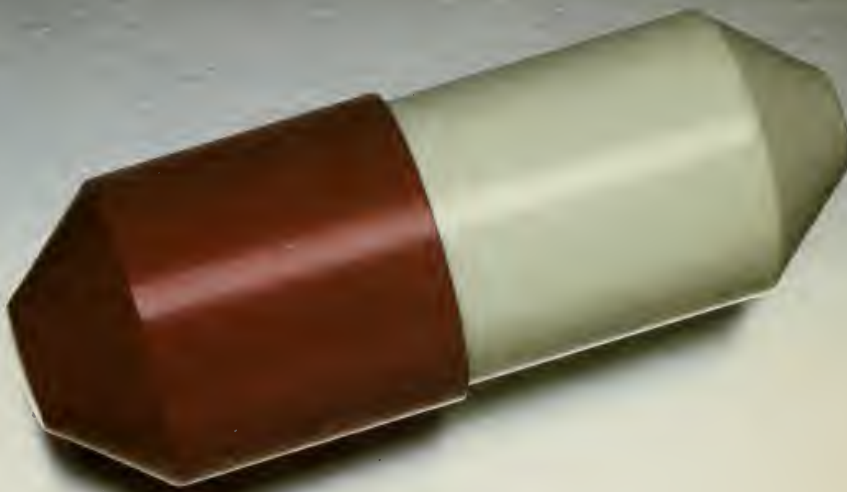
Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances, postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics), necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on Dyazide, although a causal relationship has not been established.

Supplied: Dyazide is supplied in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); In Patient-Pak™ unit-of-use bottles of 100.

In Hypertension*... When You Need to Conserve K^+

Remember the Unique Red and White Capsule: Your Assurance of SK&F Quality

Serum K^+ and BUN should be checked periodically (see Warnings and Precautions).



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Each capsule contains 50 mg. of Dyrenium® (brand of triamterene) and 25 mg. of hydrochlorothiazide.

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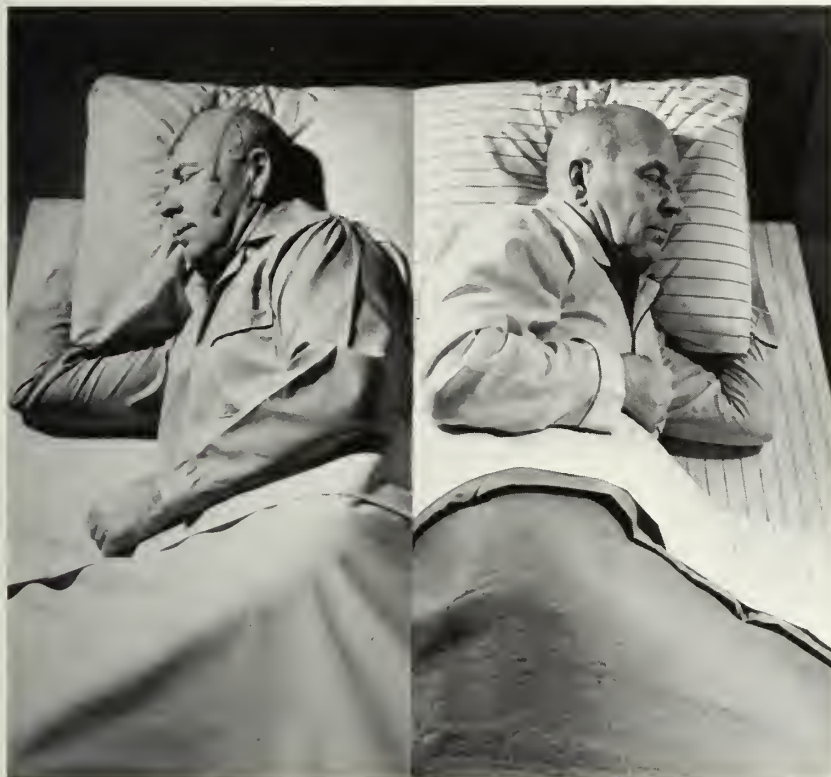
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CONFIRMED BY EXPERIENCE

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flurazepam HCl/Roche

THE COMPLETE HYPNOTIC
PROVIDES ALL THESE BENEFITS:

- Rapid sleep onset^{1,6}
- More total sleep time^{1,6}
- Undiminished efficacy for at least 28 consecutive nights^{2,4}
- Patients usually awake rested and refreshed^{7,9}
- Avoids causing early awakenings or rebound insomnia after discontinuation of therapy^{2,5,10-12}

Caution patients about driving, operating hazardous machinery or drinking alcohol during therapy. Limit dose to 15 mg in elderly or debilitated patients. Contraindicated during pregnancy.

DALMANE[®]
flurazepam HCl/Roche

References: 1. Kales J et al: *Clin Pharmacol Ther* 12:691-697, Jul-Aug 1971. 2. Kales A et al: *Clin Pharmacol Ther* 18:356-363, Sep 1975. 3. Kales A et al: *Clin Pharmacol Ther* 19:576-583, May 1976. 4. Kales A et al: *Clin Pharmacol Ther* 32:781-788, Dec 1982. 5. Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. 6. Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. 7. Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther* 21:355-361, Mar 1977. 8. Zimmerman AM: *Curr Ther Res* 13:18-22, Jan 1971. 9. Amrein R et al: *Drugs Exp Clin Res* 9(1):85-99, 1983. 10. Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. 11. Greenblatt DJ et al: *Sleep* 5(Suppl 1):S18-S27, 1982. 12. Kales A et al: *Pharmacology* 26:121-137, 1983.

DALMANE[®] ©
flurazepam HCl/Roche

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Effective in all types of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakening; in patients with recurring insomnia or poor sleeping habits; in acute or chronic medical situations requiring restful sleep. Objective sleep laboratory data have shown effectiveness for at least 28 consecutive nights of administration. Since insomnia is often transient and intermittent, prolonged administration is generally not necessary or recommended. Repeated therapy should only be undertaken with appropriate patient evaluation.

Contraindications: Known hypersensitivity to flurazepam HCl; pregnancy. Benzodiazepines may cause fetal damage when administered during pregnancy. Several studies suggest an increased risk of congenital malformations associated with benzodiazepine use during the first trimester. Warn patients of the potential risks to the fetus should the possibility of becoming pregnant exist while receiving flurazepam. Instruct patient to discontinue drug prior to becoming pregnant. Consider the possibility of pregnancy prior to instituting therapy.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, light-headedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. **Adults:** 30 mg usual dosage; 15 mg may suffice in some patients. **Elderly or debilitated patients:** 15 mg recommended initially until response is determined.

Supplied: Capsules containing 15 mg or 30 mg flurazepam HCl.

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Rhode Island Medical Journal

Vol. 67, No. 7

MISSING



Rhode Island Medical Journal

August 1984
Volume 67, Number 8

PLAY
ELVES



Mr Xai Chia Yang and his family,
Nong Khai Refugee Camp, Thailand, 1979

Mr Yang and his family in their home,
Baker Street, Providence, 1982



CONTRIBUTIONS

SOUTHEAST ASIAN REFUGEES OF RHODE ISLAND

Health Screening

A Preliminary Analysis of Birth Records

Reproductive Beliefs and Practices Among the Hmong

Psychiatric Problems, Cultural Factors and Nightmare Death

NEWSLETTER

CME CALENDAR

EDITORIAL

PRESIDENT'S PAGE

HAVE YOU HEARD?

AUG 15 1984

Seminar, September 17th



TRUE OR FALSE:

**DOCTORS ARE TRAINED IN MEDICINE,
NOT BUSINESS.**

The answer can be ambiguous. Certainly you knew enough about business to get to where you are today. However, the demands of your profession leave little time to consider more efficient and effective office management.

GIVE YOUR OFFICE MANAGER A BREAK

An office automation seminar is being offered by CompUtopia on September 17th, 7:00 P.M., at our Providence location. In addition to discussing the advantages of word processing, an extraordinary software package called Med-1 will be introduced to Rhode Island. Mr. Tom Gledhill, President of National Medical Systems and developer of Med-1, will give a short presentation.

More than 80 medical practices in Massachusetts, Vermont, New Hampshire, and New York have benefited from Med-1. Last month, National Medical Clinics picked Med-1 for its 400 offices nationwide.

USED FOR OVER 10 YEARS

The advantages of Med-1 are threefold: it's been around 10 years, so it's "time tested." Secondly, as insurance forms change, it is automatically adapted to fit. Finally, your staff is given thorough training at your offices.

For a one hour investment of time at this seminar, you can get a return that keeps on giving.

You give your patients the best care possible. Now you can do the same for your staff.

Bring your office manager! For reservations to this limited-attendance seminar, call Deborah Bellanger, CompUtopia, 274-0330.



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Newsletter

RHODE ISLAND MEDICAL JOURNAL
August 1984

Paul J.M. Healey, MD, President
Wendy J. Smith, Editor
BOSTON, MA

AUG 1984

AMA RESPONDS TO RIMS CONCERNS ABOUT MALPRACTICE CRISIS

Following intense debate at the June 17-21 annual meeting of the American Medical Association House of Delegates, the AMA Board of Trustees appointed a special task force to address the growing malpractice crisis.

The new group has been charged with establishing a public education program on the issue, helping state and county medical societies organize risk management seminars, stimulating the formation of legislative coalitions to seek tort reform, and developing potential solutions with insurance carriers.

A toll-free hotline also is to be established at the AMA headquarters in Chicago to enable physicians to consult with AMA staff on malpractice-related issues.

The action was taken as the result of resolutions from five state medical societies, including Rhode Island, on the mounting crisis. The RIMS resolution, approved at the Society's May 23 annual meeting, called for the AMA to evaluate tort reform initiatives which have survived judicial challenge and to develop model state legislation. All five resolutions were referred with "high priority" to the AMA Board of Trustees.

The AMA move is intended to stem the rapidly deteriorating professional liability situation. At a recent meeting of the Physician Insurers Association of America (PIAA), the organization which represents the 36 physician-owned malpractice carriers in the US, it was reported that 22 companies had increased their rates in 1983 and the others planned substantial premium hikes this year. A California physician-owned reciprocal, Physicians and Surgeons Insurance Exchange, (continued on page 337)

FEDS PROPOSE NEW RULES ON DRG CERTIFICATION REQUIREMENT

In response to numerous objections from physicians and hospitals, the federal Health Care Financing Administration (HCFA) has proposed several changes in the so-called certification statement now required for hospitalized Medicare patients. The proposal was published in the July 3 issue of the Federal Register.

Under the diagnosis-related group (DRG) reimbursement system, physicians currently must attest to the accuracy of the "identification of the principal and secondary diagnoses and the procedures performed." The penalty for supplying false information, the statement reads, may be "imprisonment, fine, or civil penalty." In addition to objecting to the statement's deaneaning wording, physicians have pointed out that it is impossible for them to

verify the accuracy of the International Classification of Disease (ICD) code summarizing the diagnoses and procedures performed. More than 13,000 individual code listings are possible under the ICD system.

HCFA has proposed that physicians instead be required to verify the accuracy of the "narrative descriptions" on Medicare billing forms. While the penalty clause would be eliminated from individual claim forms, physicians still would be required to sign an annual statement which acknowledges the civil and criminal penalties for falsifying information. The signed statements would be maintained by the hospital and made available to HCFA upon request.

HCFA contends that "certification and penalty statements" are part of the standard procedure for all suppliers of goods and services to the federal government or to its beneficiaries.

(continued on page 337)

JUA RECEIVES 30 PER CENT PREMIUM HIKE

The Rhode Island Department of Business Regulation has granted a substantial increase to the Medical Malpractice Joint Underwriting Association (JUA) of Rhode Island. The new rates for malpractice insurance coverage are in effect for all policies issued after June 30, 1984.

According to a JUA spokesman, there is an 11.5 per cent premium increase for the basic limits coverage of \$100,000/\$300,000 (\$100,000 per incident per year with a maximum annual payout of \$300,000 for up to three incidents), and a 16.7 per cent hike in the increased limits factor for policies covering a maximum of \$1M/\$3M. The net effect of the increase for physicians carrying both basic limits policies and increased limits coverage will be 30 per cent.

During a June 4 hearing before the Department of Business Regulation, the JUA had sought a 44.6 per cent premium increase for the basic limits coverage and a 25.9 per cent hike in the increased limits factor.

The Society was represented at the hearing by E. James Stergiou of the New York actuarial firm Woodward & Fondiller. Stergiou has testified at previous rate hearings on behalf of the Society and the Office of the Attorney General.

MEDICARE FEES FROZEN UNTIL OCTOBER 1985

In a compromise provision developed by the US House-Senate Budget Reconciliation Conference Committee, Congress in late June approved freezing Medicare payments to physicians at the June 30 level for the next 15 months.

Adopted as part of the federal budget for fiscal year 1985, the measure will require federal monitoring of every physician who does not sign a formal "participation agreement" with the Medicare program. Participating doctors must agree to accept the assignment of benefits for all services to all Medicare patients. While "partici-

MEDICARE FREEZE (continued)

pating physicians" may increase their billing charges to Medicare beneficiaries, for the next 15 months they must accept the frozen fee allowance as payment in full for all Medicare patients. When the freeze is lifted on October 1, 1985, only these participating physicians will be granted increases in their customary fee profiles.

The claims submitted by non-participating physicians, ie, those who elect to make fee decisions on a case-by-case basis, will be scrutinized for violations of the freeze.

If a pattern of increasing fees to Medicare beneficiaries is found, the physician could be liable for up to \$2,000 per violation and possible expulsion from the Medicare program for up to five years.

The Congressional action also changes the date for revising physician fee profiles from July 1 to October 1, starting next year. The provision's sponsors claim that the measure will save Medicare an estimated \$2.9 billion during the next three years.

NEW STUDY OF CANCER MANAGEMENT ANNOUNCED

Physicians and researchers from Brown University, Roger Williams General Hospital, Rhode Island Hospital, and other area hospitals recently initiated a study of cancer management in geriatric patients.

Under the study protocol, all newly-diagnosed cases of cancer of the breast, colon, and lung will be tracked from the week of diagnosis. After one year, the disposition of these patients (remission, continuing therapy, or death) will be determined from the medical records.

The study investigators also plan to ask the treating physicians to indicate which factors influenced the selection of therapies. With the prior approval of the treating physician, a small group of patients also will be interviewed.

The purpose of the study, according to Dr Francis J. Cummings, Chairman, RIMS Cancer Committee, is to determine: 1) if, as suspected, many elderly patients present at a

CANCER (continued)

later stage of disease than younger patients; and 2) if the fact of the patient's age and such limitations as restricted mobility and inadequate family support influence therapy decisions.

For further information, physicians should call Dr Cummings at 456-2060 or Dr Vincent Mor at 836-3490.

MALPRACTICE (continued)

which had insured 4,000 member physicians, recently was declared insolvent. The Florida Physicians Insurance Reciprocal, responsible for insuring one-third of the state's physicians, currently is under investigation because of concerns about its financial stability.

Joint underwriting associations (JUAs) also have come under substantial pressures to raise their rates. A request by the Florida JUA, which insures some 350 physicians and 13 hospitals, for a 77 per cent average rate increase recently was approved. The Massachusetts JUA has implemented a 42 per cent increase after its request for a 167 per cent hike was denied. In Rhode Island, the JUA in late June obtained a premium rate increase which may be as high as 30 per cent for physicians carrying the maximum coverage.

JUA representatives and insurance company officials have claimed that the increases are necessary because higher jury awards in medical liability cases have resulted in larger settlements.

DRG CERTIFICATION STATEMENTS (continued)

The AMA recently reiterated its strenuous objections to any requirement for a DRG certification statement. In a July 17 letter to HCFA Administrator Carolyn Davis, PhD, AMA Executive Vice-President Dr James H. Sammons said, "The proposed modified requirement, even though changed substantially as to procedure, remains objectionable and should be deleted." The wording was the subject of more than 30 resolutions considered by the AMA House of Delegates at its June meeting.

It has been reported that while both Dr Davis and Margaret Heckler, Secretary,

DRG CERTIFICATION STATEMENT (continued)

Department of Health and Human Services, are sympathetic to physician concerns, the DHHS Office of the Inspector General maintains that the language is necessary to prosecute fraud.

PMA AUXILIARY PRESENTS SCHOLARSHIP

The Providence Medical Association Auxiliary recently presented a \$1,000 scholarship to Edmund Billings, Jr. of Barrington. Billings, the son of Dr and Mrs Edmund Billings, Sr., is a third-year student at the University of Vermont Medical School. Contributions to the PMA scholarship fund are tax-deductible and may be sent to the PMA Auxiliary, 106 Francis Street, Providence, Rhode Island 02903.

PERIPATETICS

Members recently in the news include:

- Dr Seebert J. Goldowsky, Editor-in-Chief, Rhode Island Medical Journal, delivered a brief address on the life and times of Dr Charles V. Chapin at the May 30 designation of the State Laboratory Building as the Charles V. Chapin Building.
- The Massachusetts Association of Blood Banks recently presented its Morten Grove-Rasmussen Award to Dr Ronald A. Yankee, Medical Director, Rhode Island Blood Center, Providence, for his research on platelet and white cell transfusion therapy.
- New officers of the Rhode Island District Branch, American Psychiatric Association, include Drs William Braden, President; Paul E. Sapir, Immediate Past President; Lowell J. Rubin, President-Elect; and Robert Johnston, Secretary-Treasurer.
- Dr Raymond Moffitt, Providence, has been elected a fellow of the American Society for Lasers in Medicine and Surgery. Dr Moffitt, chief emeritus of gastroenterology, St. Joseph Hospital, recently was honored by the hospital for his contributions. Other members recognized at the hospital ceremony were Drs Guy Geffroy, David Barry, Francis Catanzaro, and Ralph Pike. The honored physicians have provided a total of more than 150 years of direction as leaders of their respective medical or surgical services.

PRACTICE MANAGEMENT QUESTION OF THE MONTH:

THROUGH THE MEDICARE MAZE: MORE ON THE FEE FREEZE

Many of the details concerning the "Medicare freeze" remained unclear at press time last month ("Impact of the Fee Freeze," RI Med J 67[7]:300). The impact of HR 4170, the Deficit Reduction Act of 1984, on all physicians, whether or not they sign formal "participation agreements" under the Medicare program, will be immediate and farreaching. Based on the report of the House-Senate conference committee which drafted the law, the following changes will be implemented by the Health Care Financing Administration (HCFA) and Blue Cross & Blue Shield of Rhode Island, the Medicare intermediary for the state.

All physicians:

The customary and prevailing charge levels recognized by Medicare will remain frozen at the level in effect on June 30, 1984 until October 1, 1985. Customary charges, according to Medicare terminology, are what the individual physician bills for a service at least 50 per cent of the time. The prevailing charge represents the average of community-wide charges by physicians of comparable training for the same service. The provision eliminates the increase scheduled for July 1984, postpones the increase previously planned for July 1985, and sets a reduced basis for revising physician fee profiles after the 15-month freeze is lifted.

Medicare carriers will be required to develop a list indicating the percentage of claims accepted on an assigned basis by all physicians. Blue Cross & Blue Shield of Rhode Island published such a list earlier this year.

Participating physicians:

The law creates a new category of "participating physicians," ie, those who agree to accept Medicare assignment for all Medicare claims for all Medicare patients. Formal "participation agreements" must be signed by the physician. The agreement remains in effect for one year and enrollment will be limited to an election period held once annually. New physicians and physicians who move to a new area can enter into an agreement at any time during the year.

During the freeze, "participating physicians" will be permitted to continue billing Medicare for their customary charges. While the customary and prevailing charges recognized by the program will be frozen, any increases in the physician's billing will be considered in revising the customary charge profile of the "participating physician" at the end of the freeze.

HCFA plans to offer several inducements to encourage physicians to sign participation agreements. Among the inducements are inclusion in a list of "participating physicians" to be provided to users of a toll-free hotline, electronic billing of claims where offered by the Medicare Part B carrier, and the ability to bill the Medicare supplemental insurance carrier (Medigap) for the full amount permitted by Medicare. The Medigap carrier in turn will collect the basic coverage from the Medicare intermediary.

Non-participating physicians:

Physicians who do not sign formal participation contracts will not be allowed to bill Medicare beneficiaries any charges during the 15-month freeze that are higher than those billed during April, May, and June 1984. Civil monetary penalties up to \$2,000 per violation and possible expulsion from the program for up to five years will be imposed against physicians who "knowingly and willfully" bill higher charges.

SEMI-ANNUAL CALENDAR OF CONTINUING
MEDICAL EDUCATION EVENTS

NOTE: Lectures and courses are listed by the date, sponsor, topic, speaker, and telephone number for additional information. Please call the contact number for specific information concerning the program.

AUGUST

- 4 Women & Infants Hosp, "Benefits of Tight Metabolic Control of the Pregnant Diabetic," Kurt Fuhrman, MD, 274-1100 ext 1584
- 11 Women & Infants Hosp, "Nutritional Support of the GYN Cancer Patient," Robert Girtanner, MD, 274-1100 ext 1584
- 13-16 Rhode Island Hospital, "Symposium on Diagnostic Imaging," speakers to be announced, 277-4707
- 14 Roger Williams General Hosp, "Breast Cancer Adjuvant Chemotherapy, 1984," Francis J. Cummings, MD, 456-2033
- 18 Women & Infants Hosp, "GYN Surgical Complications," Samir Moubayed, MD, 274-1100 ext 1584
- 28 Roger Williams General Hosp, "Evaluation and Treatment of the Hypertensive Patient," Charles Swartz, MD, 456-2033

SEPTEMBER

- 4 St Joseph Hosp, "Collagen Disease: Diagnosis and Management," Salvatore Allegra, MD, 456-3005
- 4 Roger Williams General Hosp, "The Effect of Anihypertensive Agents on Sudden Death," Drs Marc S. Weinberg, Richard J. Solomon, William Castelli, Richard Shulman, Charles Naggar, 456-2038
- 6 General Hosp-RIMC, "Epidemiology of Tuberculosis and Allied Mycobacterial Diseases," Stanley M. Aronson, MD, 464-3493
- 6 Inst of Mental Health, "Update on Research Programs at the RI Psychiatric Research and Training Ctr," Thomas Kucharski, PhD, 464-2416
- 8 General Hosp-RIMC, "Clinical Pathological Conference," Pasquale F. Finelli, MD, 464-3493
- 10 General Hosp-RIMC, "Mental Disorders & Brain Tumors," Srecko Pogacar, MD, 464-3493
- 12 Inst of Mental Health, "Forensic Issues," Manuel Soria, MD, 464-2149
- 14 Kent County Memorial Hosp, "Alcoholism in Community Hospitals," Bruno Franek, MD, 737-7000
- 15 Women & Infants Hosp, "GYN Surgical Complications," S. Moubayed, MD, 274-1100 ext 1584

SEPTEMBER

- 17 Woonsocket Hosp, "Angina," Robert J. Capone, MD, 767-3211 ext 2311
- 17 Rhode Island Hosp, "Grand Rounds (Diagnostic Radiology)," Richard Pfister, MD, 277-5184
- 20 General Hosp-RIMC, "Epidemiology of the Mycoses," Stanley M. Aronson, MD, 464-3493
- 20 Inst of Mental Health, "Borderline Personality Disorder," Richard Cote, JD; Manuel E. Soria, MD, 464-2416
- 21 Kent County Memorial Hosp, "Update: Holter, Treadmills, and Thallium Scans," Drs Felix Balasco, Hossein A. Shushtari, Oswaldo Velis, 737-7000
- 22 Women & Infants Hosp, "Cost Containment in OB/GYN," Mary Dowd Struck, Richard Showalter, 274-1100 ext 1584
- 24 General Hosp-RIMC, "Enteral Nutrition by Tube Feedings in Acute and Chronic Illness," H.T. Randall, MD, 464-3493
- 25 Roger Williams General Hosp, "The Practical Use of the Laboratory in the Diagnosis and Management of Rheumatic Disease," Mark Hockberg, MD
- 26 Inst of Mental Health, "Administration in a State Hospital," Robert R. Reidy, 464-2149
- 28 Kent County Memorial Hosp, "Gastroenterology," Richard McCallum, MD, 737-7000
- 29 Women & Infants Hosp, "Cost Containment in OB/GYN," Mary Dowd Struck, Richard Showalter, 274-1100 ext 1584

OCTOBER

- 2 St Joseph Hosp, "Dermatosis: Diagnosis and Management," Frank Veltri, MD, 456-3005
- 4 Inst of Mental Health, "Application of Neo-Therapy," Roger Richardson, PhD, 464-2416
- 4 General Hosp-RIMC, "Epidemiology of Mycoses and CNS Involvement," Stanley M. Aronson, MD, 464-3493
- 5 Kent County Memorial Hosp, "Depression in the Elderly," Jonathan Leiff, MD, 737-7000
- 9 Roger Williams General Hosp, "Immunopathogenesis of SLE," Norman Talol, MD, 456-2033
- 11 Inst of Mental Health, "Personality Disorders," Vsevolod Sadovnikoff, MD, 464-2149
- 11 General Hosp-RIMC, "Epidemiology of Genito-Urinary Infections," Stanley Aronson, MD, 464-3493
- 18 General Hosp-RIMC, "Epidemiology of Enteric Infections," Stanley M. Aronson, MD, 464-3493

OCTOBER

- 18 Inst of Mental Health, "Application of Corduroy Therapy-Mumlediweg,"
Roger Richardson, PhD, 464-2416
- 20 Women & Infants Hosp, "GYN Surgical Complications," Samir Moubayed, MD
- 23 Roger Williams General Hosp, "Update on the Mechanisms and Management
of Inflammation," Jerry Daniels, MD, 456-2033
- 24 Inst of Mental Health, "Overview on Affective Disorders," Constantine
Loures, MD, 464-2149
- 25 Woonsocket Hosp, "Rheumatology Update," Jerry C. Daniels, MD, 767-3211
- 25 General Hosp-RIMC, "Clinical Pathological Conference," Irving Beck, MD,
464-3493
- 26 Kent County Memorial Hosp, "Update on Mediators of Inflammation,"
Jerry C. Daniels, MD, 737-7000
- 27 General Hosp-RIMC, "Clinical Pathological Conference," Irving Beck, MD,
464-3493
- 27 Women & Infants Hosp, "Preconceptual Health," Robert Cephalo, MD
- 29 General Hosp-RIMC, "Peripheral Nerve Disorders in the Elderly,"
Thomas D. Sabin, MD, 464-3493

NOVEMBER

- 1 Inst of Mental Health, "Training Teams," Alan Feinstein, PhD, 464-2416
- 1 General Hosp-RIMC, "Epidemiology of Infections of the Musculoskeletal
System," Stanley M. Aronson, MD, 464-3493
- 2 Kent County Memorial Hosp, "Confusional States and Dementias," Thomas D.
Sabin, MD, 737-7000
- 5 General Hosp-RIMC, "Use and Abuse of Benzodiazepines in the Elderly,"
Norma Owens, PhD, 464-3493
- 6 St Joseph Hosp, "Diabetes Update," Frank D'Alessandro, MD, 456-3005
- 6 Roger Williams General Hosp, "A Decision Analytic Assessment of Kidney
Biopsy in Nephrotic Syndrome," Jerome P. Kassirer, MD, 456-2033
- 7 Inst of Mental Health, "Overview on Chronic Mental Disorders," Geronimo
Torres, MD, 464-2149
- 8 General Hosp-RIMC, "Clinical Neuropathological Conference," Roger S.
Williams, MD, 464-3493
- 9 Kent County Memorial Hosp, "Modes of Action in Hypertension and
Patient Types," Howard Garfinkel, MD, 737-7000
- 9 Women & Infants Hosp, "Thyroid Disease in Pregnancy," Gerard Burrow, MD
- 10 Women & Infants Hosp, "Genetics Conference," Diane Abuelo, MD, 274-1100

NOVEMBER

- 15 Inst of Mental Health, "JCAH Compliance," Briand Joyal, 464-2416
- 15 General Hosp-RIMC, "Epidemiology of Cardiovascular Infections," Stanley Aronson, MD, 464-3493
- 16 Kent County Memorial Hosp, "Medical Department Presentation," Bishnu J. Rauth, MD, 737-7000
- 17 Women & Infants Hosp, "GYN Surgical Complications," Samir Moubayed, MD, 274-1100 ext 1584
- 19 Rhode Island Hosp, "Grand Rounds (Diagnostic Radiology)," Harold Jacobson, MD, 277-5184
- 21 Inst of Mental Health, "Borderline Personality Disorders," Hugo H. Halo, MD, 464-2149
- 29 Inst of Mental Health, "Review of New Treatment Plan Form," Norman Dupont, PhD; Michael LoPresti, ACSW, 464-2416
- 29 General Hosp-RIMC, "Epidemiology of Infections of the Musculoskeletal System," Stanley M. Aronson, MD, 464-3493
- 30 Kent County Memorial Hospital, "Nutrition in 1984," Elizabeth Higgins, RD, 737-7000

DECEMBER: *A listing of continuing medical education activities scheduled for December 1984 will be published in the November issue.*

CONTINUING SERIES

Institute of Mental Health, 464-2013: Every other Thurs. starting August 2, "Difficult Case Conference"

The Memorial Hospital, 722-6000 ext 2142: Mon. and Tues., 12:15 pm, "Current Clinical Topics in Medicine and Family Medicine; Tues., 8:30 am, "Cardiology Conference"; Tues., 10:15 am, "Radiology Conference"; Weds., 8 am, "Hematology/Oncology Conference"; Weds., 10 am, "Medical Grand Rounds"; Weds., 3 pm, "Pathology Conference"; 2nd and 4th Weds., 12:15 pm, "Pulmonary Case Review"; Thurs., 12 pm, "Family Practice Grand Rounds"; Thurs., 8 am, "Surgical Grand Rounds"; Thurs., 8 am, "Orthopedic Conference"; Thurs., 4:30 pm, "Surgical Service Conference"; Monthly, time variable, "Tumor Board Review"

Roger Williams General Hospital, 456-2032: 2nd Mon., "Vascular Conference"; Weds., "Anesthesiology Conference"; Weds., "General Surgical Rounds"; 1st and 3rd Weds., "Orthopedic Conference"; 4th Weds., "Mortality/Morbidity Conference"; 4th Thurs., "Clinicopathological Conference"; Fri., 7:30 am, "Basic Science Urology Conference"; Fri., 8:30 am, "Clinical Urology Conference"; Fri., 8am, "Rheumatology Grand Rounds"; Fri., 1 pm, "Autopsy Correlative Review"

Women & Infants Hospital, 274-1100 ext 1584: Thurs., 7:45-9am, "Perinatal Conference"; Sat., 8-9 am, "Obstetrics and Gynecology Rounds"; Sat. (until Nov. 3), 9-10 am, "Maternal-Fetal Medicine Conference"; 2nd Sat., 9-10 am, "Obstetrics and Gynecology Journal Club"

Rhode Island Medical Journal

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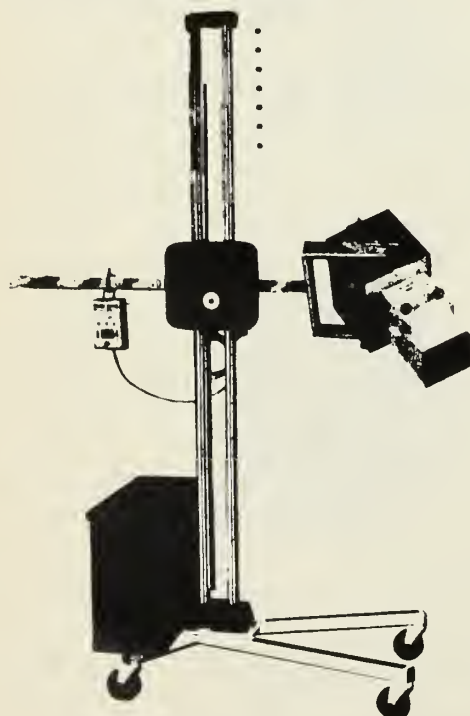
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Treatment of physicians for alcohol addiction shows a favorable outcome in 83 per cent of cases, and treatment of physicians for drug addiction has a 95 per cent success rate. More than 70 per cent of the physicians entering treatment return to the active practice of medicine.

The Rhode Island Medical Society Committee on Impaired Physicians, chaired by Dr Herbert Rakatansky, meets monthly. It is a standing committee of the Society charged with "helping physicians whose professional judgments and capabilities are impaired by their difficulties with chemical dependency or other illnesses."

The Committee handles inquiries in *complete confidence*. If you know of a physician who needs an advocate and support in obtaining necessary treatment, please call or write Dr Rakatansky c/o The Committee on Impaired Physicians, Rhode Island Medical Society, 106 Francis Street, Providence 02903 (401/331-3207).

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COVER *Mr Xai Chia Yang and his family photographed in a Thai refugee camp in 1979 and three years later in their Providence home*

Cover photograph by Ellen Kuras; photographs on pages 354, 362, 364, and 365 by Ki Ho Park, Rhode Island School of Design

Update

The Ocean State Master Health Plan

August 1984

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Have you heard? . . .

(Continued from page 367)

analyzer® offers a wide range of fully-automated tests including general and special chemistries, enzymes, endocrine functions, therapeutic drug monitoring, toxicology, electrolytes, immunology, and coagulation tests. It also features a new built-in ion selective electrode capability which, in addition to the sodium and potassium tests presently available, can be expanded to accommodate new electrode methods as they are developed. Chloride and total carbon dioxide electrodes are under commercial development.

Another improvement is the inclusion of dual, independent needles at the sample filling station. This permits test batteries to be performed simultaneously, increasing maximum production to more than 180 tests an hour. A new detector now determines if the sample volume for an assay is adequate before the test is performed. Processing stops automatically if the sample falls below preset limits, thus helping to ensure accurate results and to prevent reagent waste.

• • •

Utilization of oral theophylline preparations can produce potentially serious, life-threatening intoxication, according to a report in the April 1984 *Archives of Internal Medicine*. Clinicians from the University of Colorado Health Sciences Center in Denver report on 22 patients, ranging from 46 to 86 years of age, who were hospitalized as a result of oral theophylline intoxication. Symptoms include anorexia, nausea, vomiting, abdominal pain, and tremulousness. Virtually all of the episodes were associated with cardiac arrhythmias, and three patients suffered grand mal seizures. The toxic effects in these cases apparently resulted from an incomplete understanding by both patients and physicians of the appropriate clinical use of the drug. Physicians were cautioned to urge conservative dosage and to watch for potential drug interactions.

• • •

According to a report published in the March 1984 issue of *The Archives of General Psychiatry*, researchers from the New York University Medical Center have confirmed the presence of altered brain metabolic activity in schizophrenic patients. Doctor Tibor Farkas and his colleagues compared the brain metabolism of 13 diagnosed schizophrenics with that of 11 normal controls.

Under study was glucose metabolism in both the frontal and posterior regions of the brain. Although the researchers found that the mean glucose metabolic rate was markedly slower in the frontal regions of the brain among the schizophrenic patients, the slower rate apparently is not due to any anatomic difference between the groups. These findings underscore the continuing puzzle of schizophrenia research, eg, that the abnormal behavior of schizophrenic patients appears not to be associated with any anatomic abnormality in the brain.

• • •

Cochlear implants are finding increasing acceptance and application by otolaryngologists, according to a report in the March issue of the *Archives of Otolaryngology*. The implants are prosthetic devices that assist patients who have certain forms of profound hearing loss. Researchers from the University of Washington point out that the devices were regarded with universal skepticism by otolaryngologists only ten years ago. While a number of questions remain unanswered, including the effectiveness of implants for patients who have had little or no experience with sound, the utilization of the prosthesis is gaining wider acceptance.

• • •

Hair regrowth was seen in 25 of 48 patients participating in a study of the effectiveness of 1 per cent minoxidil solution, according to a study reported in the April 1984 issue of *Archives of Dermatology*. Doctor Virginia C. Weiss and her colleagues at the University of Illinois in Chicago note that the hair regrowth was cosmetically acceptable to 11 of the patients responding to therapy. A potent peripheral vasodilator, minoxidil apparently stimulates hair growth by affecting the blood flow, the immune system, or through its direct effect on hair follicles.

• • •

Intravenous Calan® (verapamil HCl) is now available from Searle Laboratories in new vials which are designed for easier handling than the previously available glass ampuls. Calan IV® is a cardiac agent often used in emergency situations. The glass ampuls required a rather cumbersome process of breaking a glass seal at the neck of the ampul before drawing the drug out in a syringe. With the new vials, the physician needs only to remove the protective plastic cap and pierce the rubber stopper to prepare the syringe for making an injection. ■

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Brief Summary: Consult the package literature for prescribing information.

Indications and Usage: Cefaclor* (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae* (*Diplococcus pneumoniae*), *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococcus).

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Cefaclor.

Contraindication: Cefaclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Cefaclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: General Precautions—If an allergic reaction to Cefaclor occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Cefaclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when anti-globulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Cefaclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Cefaclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinistix® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy—Pregnancy Category B—Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Cefaclor. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers—Small amounts of Cefaclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours, respectively. Trace amounts were detected at one

Some ampicillin-resistant strains of *Haemophilus influenzae*—a recognized complication of bacterial bronchitis*—are sensitive to treatment with Cefaclor.^{1,6}

In clinical trials, patients with bacterial bronchitis due to susceptible strains of *Streptococcus pneumoniae*, *H. influenzae*, *S. pyogenes* (group A beta-hemolytic streptococci), or multiple organisms achieved a satisfactory clinical response with Cefaclor.⁷

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hour. The effect on nursing infants is not known. Caution should be exercised when Cefaclor* (cefaclor, Lilly) is administered to a nursing woman.

Usage in Children—Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Cefaclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100), Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis, arthralgia, and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Cefaclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain—Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic—Slight elevations of SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic—Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal—Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

(061782R)

*Many authorities attribute acute infectious exacerbation of chronic bronchitis to either *S. pneumoniae* or *H. influenzae*.

Note: Cefaclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

References

1. Antimicrob. Agents Chemother. 8:91, 1975.
2. Antimicrob. Agents Chemother. 11:470, 1977.
3. Antimicrob. Agents Chemother. 13:584, 1978.
4. Antimicrob. Agents Chemother. 12:490, 1977.
5. Current Chemotherapy (edited by W. Siegenthaler and R. Lilly) 11:860. Washington, D.C. American Society for Microbiology, 1978.
6. Antimicrob. Agents Chemother. 13:861, 1978.
7. Data on file, Eli Lilly and Company.
8. Principles and Practice of Infectious Diseases (edited by G.L. Mandell, R.G. Douglas, Jr. and J.E. Bennett), p. 487. New York: John Wiley & Sons, 1979.

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Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285. Eli Lilly Industries, Inc., Carolina, Puerto Rico 00630.

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RHODE ISLAND MEDICAL SOCIETY FOUNDATION

The officers and Council of the Rhode Island Medical Society established the RIMS Foundation in 1983 to promote charitable, educational, and scholarly endeavors in the service of medical care and public health.

While these have always been the basic objectives of the Society, tax laws make the new RIMS Foundation the appropriate vehicle for furthering them in the 1980s. Among the activities of the Foundation will be:

- public information programs to promote awareness of the malpractice crisis and an understanding of other problems facing America's health care system
- continuation of the long-standing work of the Benevolence Fund to help needy physicians and their families
- scholarships, grants, and loans to medical students
- support for other educational and scholarly endeavors, including continuing medical education activities and the Society's Library

Already a series of seminars to address malpractice issues is in the planning stages for this fall.

Because the Foundation is recognized as a 501.c.3. organization under the Internal Revenue Code of 1954, all contributions to the RIMS Foundation are tax-deductible. (In contrast, contributions to RIMS itself are not. Only your annual RIMS dues are tax-deductible since they represent a professional business expense.)

Below are the names of our colleagues who have contributed to the Foundation all or part of their share in the recent settlement of the *Barry* case. To date, this effort alone has raised more than \$37,000 for the Foundation.

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Before prescribing, see complete prescribing information in SK&F CO. literature or PDR. The following is a brief summary.

WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Anti-hypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

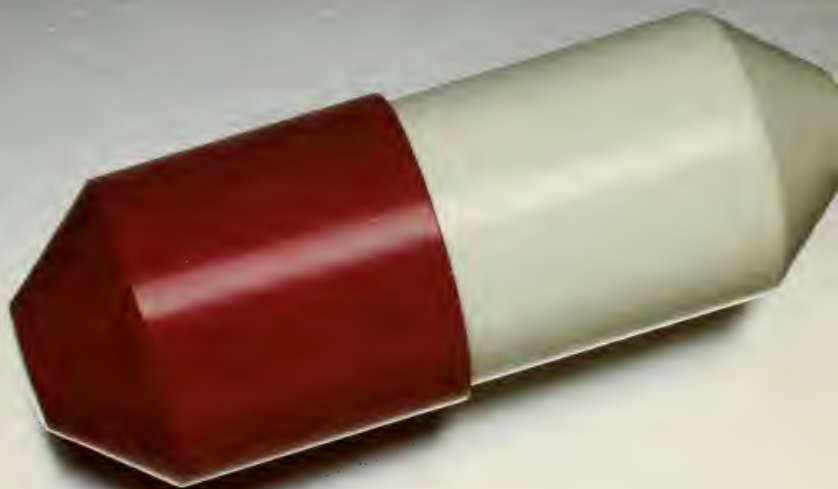
Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances, postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics), Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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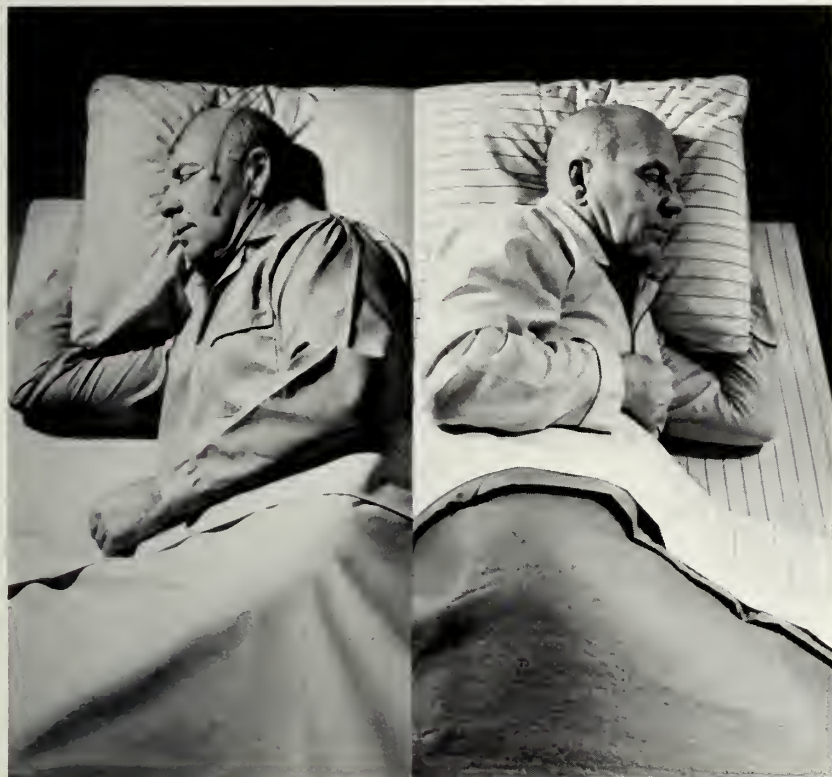
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Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, light-headedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

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Rhode Island Medical Journal

September 1984
Volume 67, Number 9

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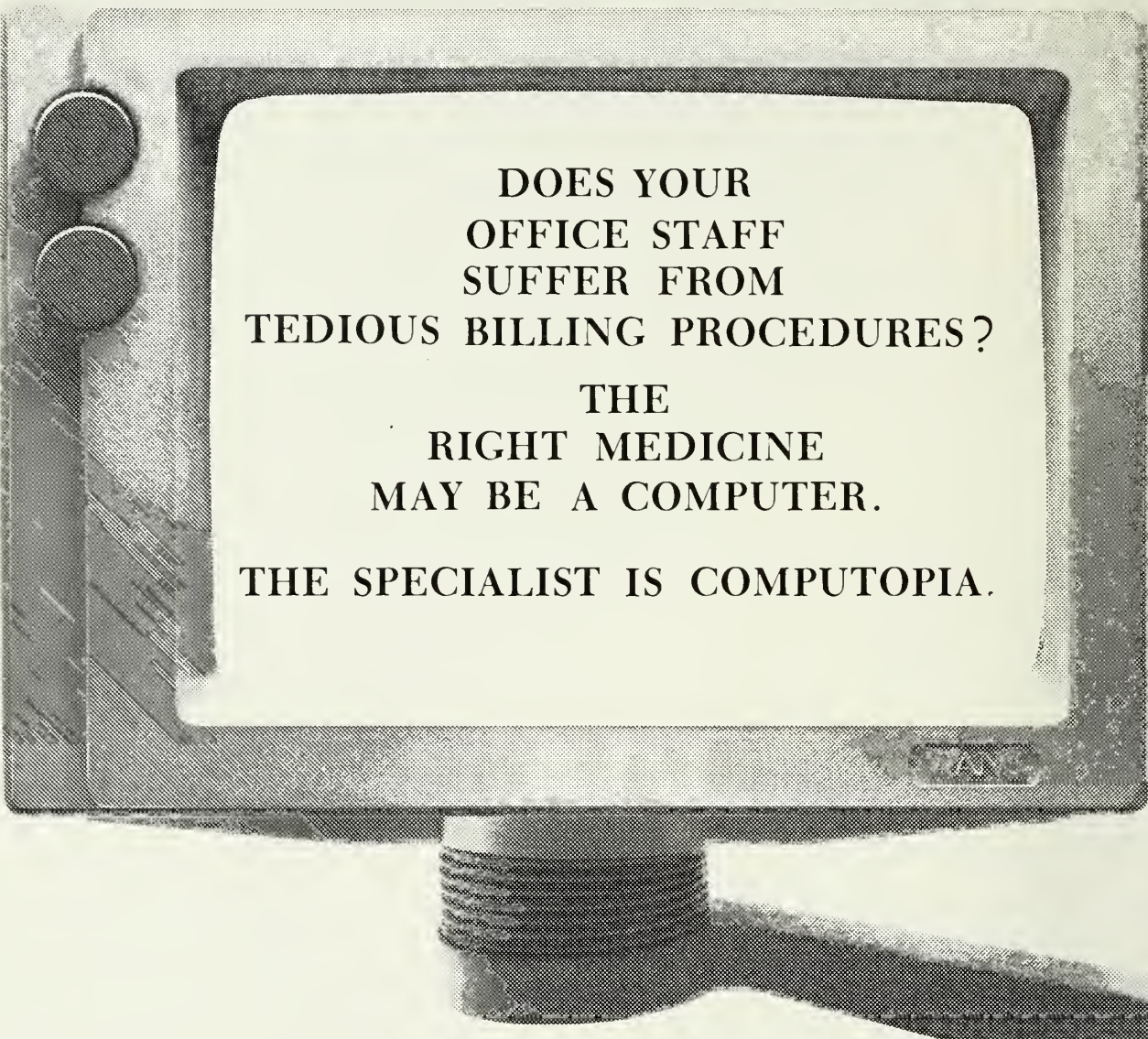
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Health promotion at the
worksite — see pages 391 and 395



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RHODE ISLAND MEDICAL JOURNAL
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NEW BLUES PAYMENT SYSTEM ANNOUNCED AT COUNCIL MEETING

SEP 25 1984

As the result of complaints from RIMS members, the Board of Directors of Blue Cross & Blue Shield of Rhode Island recently authorized a new reimbursement method which should ease some of the cash flow problems faced by many of the state's physicians. RIMS President Dr Paul J.M. Healey described the new program during a recent meeting of the Society's Council.

Under the Provider Cash Management Program, which Dr Healey emphasized would be voluntary, physicians will receive semi-monthly payments during the year based on their reimbursement from the Blues during the previous calendar year. If a physician received \$24,000 from Blue Cross & Blue Shield in 1983, for example, he or she would receive 24 payments of \$1,000 during 1984 plus a 6 per cent inflation factor. If the physician generates more or less than \$1,000 during any particular two-week

period, the adjustment would be made on the next payout. In all cases, however, the physician will be paid the higher of: 1) the actual claims settlement; or 2) the average settlement based on the 1983 claims experience.

In other actions at its August 6 meeting, the Council:

- endorsed a study recently initiated by Brown University, Roger Williams General Hospital, Rhode Island Hospital, and other area hospitals to determine if factors related to the age of the patient affect therapeutic decisions concerning cancer management.
- endorsed the Colorectal Health Check of the American Cancer Society and its local divisions.

(continued on page 383)

RIMS MEETS WITH CHAFEE STAFF ABOUT MEDICARE AND MALPRACTICE REFORM

The RIMS Executive Committee recently held the second in a series of meetings scheduled with Christine Ferguson, a legislative aid from Senator John Chafee's office, to discuss the fiscal problems faced by the Medicare program, the malpractice crisis, and anti-trust restraints against the profession.

Present at the July 17 session were Drs Paul J.M. Healey, President; Charles P. Shoemaker, Jr., Immediate Past President; John J. Cunningham, AMA Delegate; Frances Conklin, President, Providence Medical Association; David S. Greer, Dean, Brown University Program in Medicine; William A. Reid, Rhode Island Group Health Association; Dr Norman A. Baxter, RIMS Executive Director; Wendy J. Smith and Dr Newell E. Warde, RIMS Assistant Executive Directors.

During a wide-ranging meeting covering physician reimbursement issues, it was

emphasized that doctors and their patients have become more and more frustrated by continually shifting Medicare requirements, including such arbitrary restraints as DRGs, fee freezes, and other piecemeal approaches to fiscal reform. The group also agreed that the "system rewards inefficiencies and some questionable medical practices." Many current problems, including the physician oversupply and inappropriate distribution of some specialists, were attributed directly to disincentives encouraged by the Medicare program and other third-party mechanisms.

Additional sessions will be scheduled to analyze the malpractice crisis, address anti-trust considerations, and develop potential solutions for the Senator's consideration. Ms. Ferguson also is meeting with representatives from the Hospital Association of Rhode Island (HARI) and groups of Medicare beneficiaries.

COUNCIL CONTINUES TO GRAPPLE WITH MALPRACTICE CRISIS

The growing impact of the malpractice crisis on physicians and their patients continued to absorb the Council's attention at its August 6 meeting.

As reported in the August Newsletter (RI Med J 67[8]:300), the Medical Malpractice Joint Underwriting Association (JUA) of Rhode Island recently implemented a rate hike which will result in a 30 per cent premium increase for many of the state's physicians. The Council also was told that the malpractice crisis emerged as the principal agenda item at the June 1984 AMA annual meeting, primarily as the result of resolutions submitted by the Society and four other state delegations.

Among the issues considered by the Council at its three-hour session were:

- Sources of coverage: In response to the most recent JUA premium increase, a growing number of inquiries have been received from RIMS members regarding alternative sources of professional liability insurance. Although St Paul reportedly has been authorized to sell coverage in the state, the company has yet to market a physician package. Society President Dr Paul J.M. Healey also told the Council that preliminary discussions have been held with an actuarial consultant regarding the feasibility of establishing an offshore insurance company to provide coverage for Rhode Island physicians.
- Malpractice commission: The Rhode Island General Assembly in 1984 approved the establishment of a 15-member commission charged with addressing the professional liability problem. Although the group must report its findings by February 1, 1985, Dr Healey told the Council that no action apparently has been taken to appoint members or activate the commission. The Society formally has protested this lack of action to the House and Senate leadership.
- Educational seminars and risk management activities: The Rhode Island Medical Society Foundation plans to sponsor a

series of educational seminars and programs on risk management later this year. As part of the planning process, Dr Healey said that the Foundation will send several representatives to a September 1984 seminar on risk management and tort reform organized by the Council of Medical Specialty Societies (CMSS). The CMSS meeting will feature recognized authorities in the field.

DRGs, MEDICARE, AND PROPRIETARY HOSPITALS TO BE ADDRESSED AT NEWPORT MEETING

Margaret Heckler, Secretary, US Department of Health and Human Services, will be the keynote speaker at a September 17-18 meeting organized by the RI Chapter, Healthcare Financial Management Association. The group is affiliated with the Hospital Association of Rhode Island.

Also featured at the Newport meeting will be Sheila Burke, RN, the Congressional staffperson responsible for evaluating all health-related proposals considered by the US Senate Finance Committee; Michael Bromberg, Executive Director, Federation of American Hospitals; and David A. Winston, a Washington DC consultant who headed President Reagan's 1980 transition team on health. Considerations of diagnosis-related group based reimbursement, the impact of for-profit hospitals, and Medicare financing are expected to dominate the seminar.

The meeting is open to all interested physicians and other health care professionals. For further information, please call Richard C. Heckel at HARI (401/421-7167).

BLUES TO CONVERT TO NEW CODING SYSTEM

Effective January 1, 1985, physicians submitting Medicare claims to Blue Cross & Blue Shield of Rhode Island will be required to use the Current Procedural Terminology, 4th Edition (CPT-4), developed by the American Medical Association. CPT-4 has been incorporated into a new coding system required by the Health Care Financing Administration for all Medicare intermediaries.

Because of copyright restrictions, copies of CPT-4 must be ordered directly from the

NEW CODING SYSTEM (continued)

American Medical Association, Order Department (OP-341), PO Box 10946, Chicago, Illinois 60610. The manual costs \$25 per copy plus a \$4.50 handling charge.

COUNCIL MEETING (continued)

- urged Society members to support a \$5 million bond issue scheduled for the November ballot to finance a statewide emergency telephone system. During its 1984 session, the Rhode Island General Assembly approved establishment of a 911 emergency system subject to voter approval of the referendum. Emphasizing that Rhode Island is one of the few jurisdictions in the country without an emergency access telephone number, the Society has long advocated its establishment.
- noted that Dr Paul T. Welch has agreed to serve as chairman of the Mediation Committee. Dr Richard P. Sexton recently was appointed to complete the unexpired term of the late Dr Melvin D. Hoffman on the committee and Dr Thomas Perry, Jr. will replace Dr Frank W. Sullivan whose

term will expire this year.

- noted the appointment of Dr. Stanley M. Aronson as chairman of the Library Committee.
- approved a position paper on Medicare reform for submission to the Society's House of Delegates at its September 19 meeting. The statement encourages the Rhode Island Congressional delegation to seek "substantive, far-sighted, and fair solutions to the problems resulting from the rising costs of medical care."
- approved a proposed 1985 budget for submission to the Society's House of Delegates at its September meeting.
- noted that the Rhode Island Medical Society Foundation has received more than \$37,000 in donations and \$3,500 in pledges within the past two months. The contributions, made by plaintiffs of the recently-settled Barry case, will be used to finance educational and research activities concerning malpractice, including a planned series of seminars on risk management.

PRACTICE MANAGEMENT QUESTION OF THE MONTH:

HOW WILL NEW REIMBURSEMENT MECHANISMS AFFECT MY PRACTICE?

Even after the Medicare fee freeze is lifted on October 1, 1985, it is likely that physicians will be subjected to increasingly restrictive reimbursement policies. Unlike hospital services for Medicare inpatients (Medicare Part A) which are covered by the financially-troubled Medicare trust fund, the costs of physician services to these patients under Medicare Part B are financed through a combination of beneficiary premiums (25 per cent) and general tax revenues (75 per cent). At an annual cost of \$25 billion, Medicare Part B has become the country's third largest domestic program and the subject of growing Congressional scrutiny.

As required by the Deficit Reduction Act of 1984, the Health Care Financing Administration (HCFA) must report on the feasibility of a prospective payment system for physicians by next July. While the exact nature of the HCFA proposals remains unknown at this point, the agency probably will endorse a diagnostic-related group (DRG) based reimbursement system for physicians. Many of the proposals under HCFA consideration, as outlined in a recent speech by an agency official to the Council of Medical Specialty Societies, foreshadow ominous news for physicians from at least two perspectives. First, service plans and commercial carriers frequently use Medicare reimbursement policies as the basis for their own procedures for private patients. Second, many of these proposals may well exacerbate the relationship between hospital medical staffs and their hospitals.

HCFA is addressing the problem from three perspectives:

Who to pay:

Although there currently is a clear separation between payments for services provided by hospitals and physicians, the following HCFA "study options" would eliminate this distinction. HCFA is exploring alternative plans which would result in one payment to: 1) the hospital, which would be responsible for allocating reimbursement to physicians; 2) the primary care provider, who would pay the hospital, any specialists, and providers of ancillary services; 3) the hospital medical staff, which would redistribute the money among its members for their professional services; or 4) the Medicare fiscal intermediary (Blue Cross & Blue Shield of RI), which would pay the hospital and individual physicians from the lump sum reimbursement.

Regardless of the option selected, the implementation of a single payment to physicians and hospitals would have significant repercussions for medical practice. It has been argued that making the payment to the hospital would dilute the physician's role as a patient advocate. If the payment were made to the attending physician, who in turn would be required to pay any consultants, the utilization of appropriate specialists may well decline and patient services suffer as a result. Moreover, because a combined payment to doctors and hospitals would be difficult to administer without mandatory assignment, it is likely that all physicians would be required to accept Medicare reimbursement as "payment in full" for their professional services.

What to pay for:

In an effort to refine the DRG classification system, HCFA is attempting to define what constitutes a "medical episode." Among the unresolved issues are whether the episode would include only the care provided during hospitalization, pre-admission testing, post-discharge therapy, or all three. If inpatient services were handled under the DRG payment while pre-admission and post-discharge services were not, there could be a significant effort to transfer hospital care to an ambulatory setting. Other problems associated with this approach include: 1) developing appropriate models for medical, as compared to surgical, episodes; 2) determining payment methods for such outpatient services as dialysis and diabetic management; 3) adjusting the reimbursement scale to reflect the severity of disease; and 4) establishing an equitable payment for teaching services.

How much to pay:

The variations in physician fees have presented a major problem in developing DRGs for professional services. The amounts charged for the "same service" differ widely according to the physician's specialty, years in practice, and geographic location.

One method of reimbursing physicians that has attracted increasing attention from both Congress and HCFA is that of fee schedules based on relative value scales (RVS). Under this approach, services and procedures are assigned an RVS rating based on their value, difficulty, or cost. Although an RVS is not a fee scale, it easily can be converted to one simply by multiplying the RVS value by a dollar factor. As an example, an insurer has determined that procedure A is three times as difficult to perform as procedure B. If procedure A were assigned an RVS value of 3, and the conversion factor were \$30, the fee would be \$90. Although the best known RVS was developed by the California Medical Association in the mid-1950s, the US Supreme Court has ruled that their use by medical societies constitutes "restraint of trade." However, insurance companies continue to utilize relative value scales as a basis for payment.

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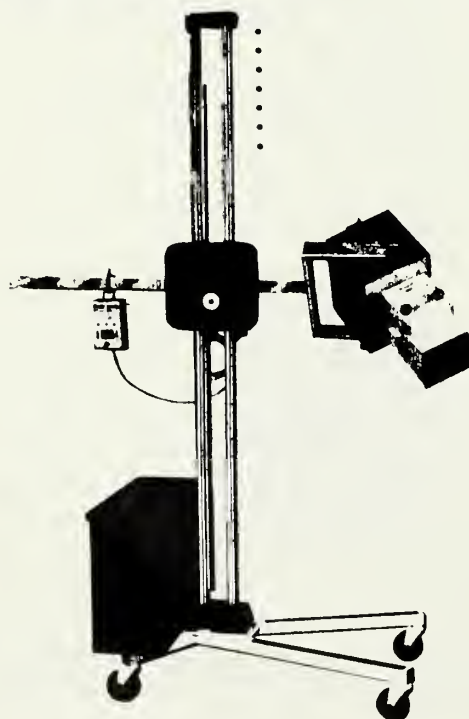
**Do You Know an
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Treatment of physicians for alcohol addiction shows a favorable outcome in 83 per cent of cases, and treatment of physicians for drug addiction has a 95 per cent success rate. More than 70 per cent of the physicians entering treatment return to the active practice of medicine.

The Rhode Island Medical Society Committee on Impaired Physicians, chaired by Dr Herbert Rakatansky, meets monthly. It is a standing committee of the Society charged with "helping physicians whose professional judgments and capabilities are impaired by their difficulties with chemical dependency or other illnesses."

The Committee handles inquiries in *complete confidence*. If you know of a physician who needs an advocate and support in obtaining necessary treatment, please call or write Dr Rakatansky c/o The Committee on Impaired Physicians, Rhode Island Medical Society, 106 Francis Street, Providence 02903 (401/331-3207).

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COVER

Health promotion on the job: An aerobics class held in the Statewide Health Coordinating Council (SHCC) room of the Rhode Island Department of Health.

Photograph courtesy of Louis A. Marciano, RIDH Office of Health Promotion.

A Picture of Health

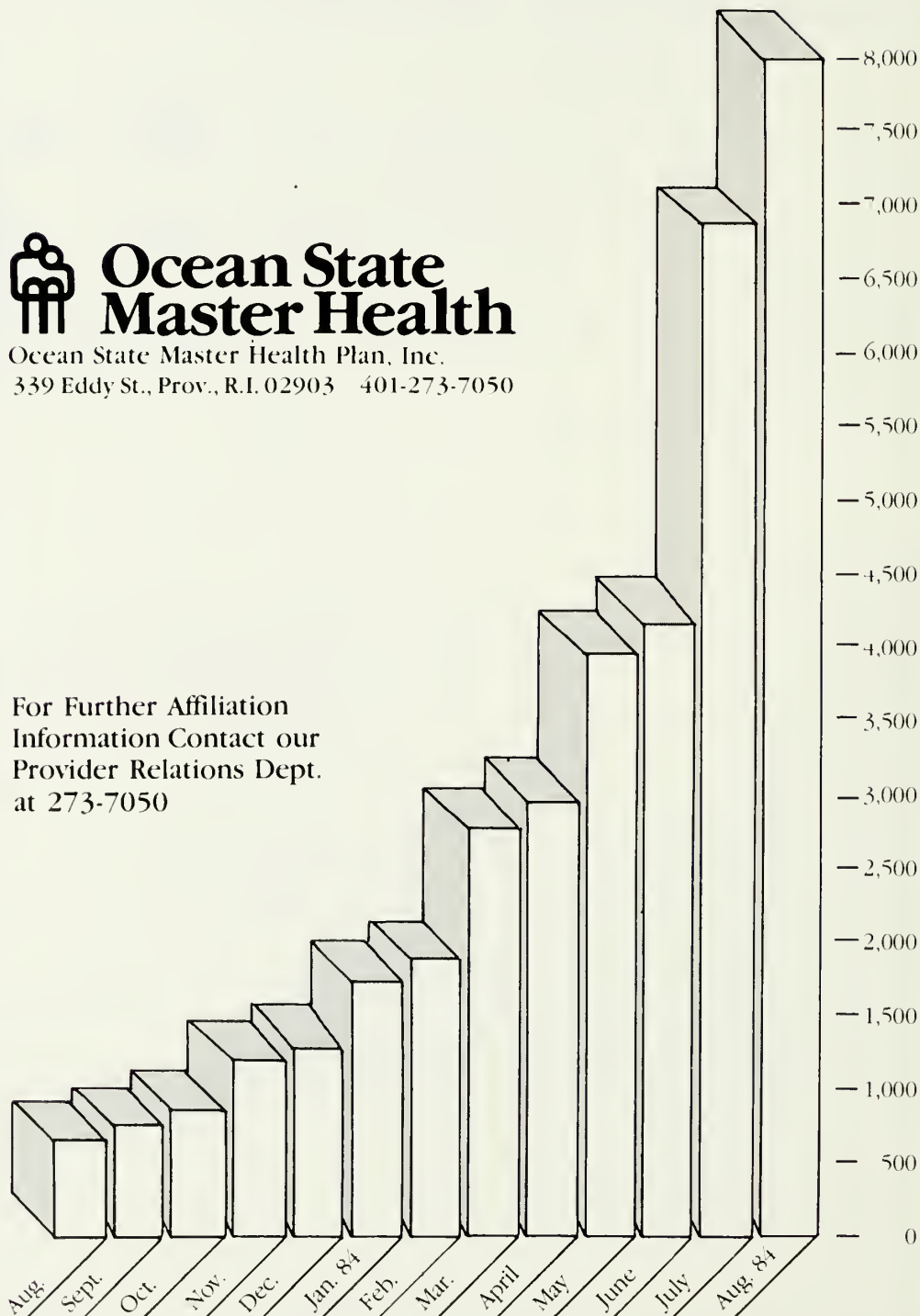
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The "Wellness Check" Program of the Rhode Island Department of Health

Elsewhere in this *Journal* appear the results of a 1981 Rhode Island Department of Health sample survey of all employers in the state concerning "health promotion activities" at the worksite. The scope of these activities ranges from screening programs designed to identify specific dysfunctions, such as glaucoma and hypertension, to more comprehensive interventionist approaches aimed at a healthier lifestyle. As expected, the survey reveals that larger businesses and manufacturers are four times as likely to sponsor health-promotion programs as the smallest firms. Because most persons are employed by comparatively small organizations, these findings suggest that it may be difficult to reach a significant proportion of the working population through job-related programs.

It is likely, however, that growing numbers of patients will become involved with at least one work-related "health promotion" program. As the expenses for health insurance reach unprecedented levels for many employers, the business community has expressed understandable interest in stemming health-related costs. All of the firms in the 1981 survey felt that important benefits are derived from preventive strategies. Most employers believe that, in addition to increasing employee morale, health promotion programs reduce the incidence of disease, absenteeism, and compensation claims. Moreover, nearly half of the respondents said that organized corporate activities may well decrease costs for the employer because of improved employee productivity, fewer health and life insurance claims, and lower premium payments for workers' compensation, disability, and health insurance.

Using data from this and other surveys, the health department developed an innovative program to help corporate officials encourage healthier lifestyles by their employees. More than 25,000 Rhode Island workers and 10,000 adolescents have participated in the "Wellness Check"

program organized by the Rhode Island Department of Health Office of Health Promotion. Individual participants complete a 16-page questionnaire covering their diet, exercise levels, alcohol and cigarette consumption, use of seat belts, moods and stress, exposure to toxic substances, and family history. Other screening measures, such as glaucoma tests, blood samples, and hypertension screening, also are performed at health fairs. The employee receives a computer assessment of his overall health status and suggestions for improvement. If any dysfunctions are identified during the screening process, the employee is referred to his own physician for evaluation and therapy.

From the perspective of the sponsoring organization, however, the crux of the program involves an aggregate statistical report concerning the firm's employees in each of the health risk categories evaluated. The report also compares the health risks faced by the corporation's workers with those of the other 25,000 Rhode Islanders who have been assessed under the program. More importantly, the health department works closely with personnel managers by providing a link to local agencies, such as the American Red Cross and Rhode Island Division of the American Cancer Society, which organize on-site programs. The "Wellness Check" evaluation is performed at no cost to the sponsoring organization.

Highly regarded as a prototype, the "Wellness Check" program currently is used by 151 state and local health departments throughout the United States. The Office of Health Promotion has established a national network for data collection, thus facilitating comparisons of the health status of Rhode Islanders with employees in other states. It also has applied for a grant from the Centers for Disease Control to perform a six-state comparative evaluation of the health dangers faced by adolescents.

Wendy J. Smith

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PRESIDENT'S PAGE



First, the good news . . .

Outside forces continue to affect physicians and their traditional patterns of fee-for-service and contacts with patients. Within the past month, two startling decisions were made which will leave a permanent imprint on how doctors are paid for their professional services. These will result in a mixed bag of "good news/bad news."

First, what appears to be a major improvement in the payment mechanism of Blue Cross & Blue Shield of Rhode Island was approved by that corporation's Board of Directors on July 26. Called the Provider Cash Management Program, the proposed solution is aimed at eliminating one of the most common complaints from physicians, namely, an inconsistent cash flow resulting from uneven Blues payments. Without finger-pointing or trying to place blame on past problems, either with Blue Shield or physicians' offices, the net result has been all too frequent cash shortfalls for practicing doctors. Some have had to take bank loans or borrow from other sources to make payroll, pay rent, and purchase supplies. Others have claimed these difficulties have prompted them to become "non-participating" providers. At any rate, the proposed solution should help resolve this problem.

Simply stated, the Provider Cash Management Program will reimburse doctors in regular semi-monthly payments based on the average settlements for the previous year, plus a six per cent allowance for changes in physician charges, utilization, and mix. The program will be entirely *voluntary* on the physician's part and mechanically will add little or no additional burden on office staff.

We should applaud this effort on the part of Blue Shield and hope that it fulfills its promise of alleviating a major complaint by physicians in Rhode Island. It represents a "first" in the country and will be watched carefully by other Blues plans nationwide.

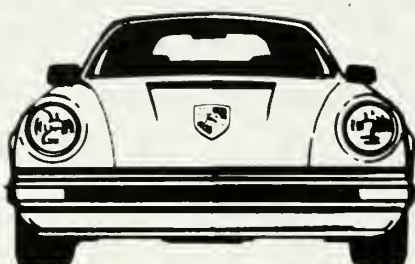
And now, the bad news . . .



Paul J. M. Healey, MD

The new provisions for physician reimbursement under Medicare have become a reality under the Deficit Reduction Act of 1984 (PL 98-369) enacted on July 18, 1984. This new law: 1) freezes reimbursement levels from July 1, 1984 to September 30, 1985; 2) creates a two-level physician grouping of "participating" and "non-participating" doctors; 3) provides certain incentives to encourage physicians to sign participation agreements; 4) prohibits fee increases by "non-participating" physicians during the 15-month period; and 5) requires potentially severe penalties for violation of the fee freeze.

Although the physician has the *option* of signing a participation agreement, it is essential that all doctors become well informed as to the detailed provisions of this law and its consequences for the treatment and billing for medical services to Medicare recipients. The AMA published an explanatory booklet on July 30 which should be required reading for all physicians.



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Health Promotion Activities at the Worksite: A Rhode Island Business Perspective

Such Activities Show Promise as an Effective Means of Promoting Health and Improving Productivity

Bruce C. Kelley, PhD
David M. Gute, PhD
Peter P. Potthoff, MS
William J. Waters, PhD

A number of articles and papers concerning employer-sponsored health promotion activities have appeared recently in magazines, business publications, and professional journals. Many publications have advocated the development of such programs,¹⁻³ and implementation guidelines have been suggested by others.⁴⁻⁶

While anecdotal information has been reported on programs organized by large corporations, there are almost no systematic data available on health promotion activities sponsored by different types of employers across the country or in different regions. To determine the extent of corporate involvement in Rhode Island and the perceived benefits of health promotion activities to employers, the Rhode Island Department of Health in 1981 conducted a sample survey of

all firms in the state. The results of the Rhode Island survey also were compared to a similar study conducted in California.⁷

Methodology

The Rhode Island Department of Employment Security provided a list of all employers categorized by size, ie, firms with 20-49 workers, 50-99, and 100 or more. Because many small businesses do not sponsor health promotion activities, firms employing less than 20 employees were not included in the survey. Also excluded were two major employers, the State of Rhode Island and the federal government. The Department of Employment Security selected a random sample of 25 per cent of the firms with 20-49 employees and 25 per cent of the employers with 50-99 workers. All firms with 100 or more employees were surveyed.

A survey instrument consisting of nine multiple-response questions was sent to 952 Rhode Island employers during the week of July 3, 1981. Non-respondents were resurveyed seven weeks later. The aggregate response rate was 56 per cent although the response rate for firms with 100 or more employees was slightly higher at 59 per cent (Table 1).

Results

In Rhode Island, there appears to be a direct positive correlation between the size of the firm and whether it sponsors an organized medical program, offers diagnostic or screening programs to its employees, or provides preventive services and health promotion programs. Table 2 reveals that larger firms are more likely to sponsor organized medical or health promotion pro-

From the Rhode Island Department of Health, Providence, Rhode Island

Bruce C. Kelley, PhD, Consultant, Meidinger Health Risk Management, Inc, Minneapolis, Minnesota. At the time of this writing, Doctor Kelley served as Chief, Office of Health System Planning, Rhode Island Department of Health.

David M. Gute, PhD, Director, Research and Epidemiology, Massachusetts Department of Health, Boston, Massachusetts.

Peter P. Potthoff, MS, Liberty Mutual Insurance Company, Boston, Massachusetts.

William J. Waters, PhD, Assistant Director for Health Policy, Rhode Island Department of Health, Providence, Rhode Island.

Table 1. — Count of Sampled Firms and Response Rate

Sample Size	Firms with 20-49 Employees	Firms with 50-99 Employees	Firms with 100 or More Employees	Total
Number sampled	354	127	471	952
Number responded	196	54	280	530
Per cent responded	55.37	42.52	59.45	55.67

grams. While only six per cent of the businesses with 20-49 employees reported any organized health promotion activities, approximately 18 per cent of those with 50-99 employees, and 24 per cent of the firms with 100 or more workers sponsor an identifiable program.

Large firms also are more likely than smaller ones to offer screening tests, diagnostic examinations, or both to their employees. Regardless of the size of the employers, however, few sponsor diagnostic or screening programs designed to identify the early stages of specific health problems. Approximately 18 per cent of the respondents sponsor routine physical examinations, 14 per cent hypertension screening, and eight per cent tuberculosis screening. Screening programs for glaucoma, diabetes, or breast cancer are even less common. Only three per cent of the respondents offer a formal health risk appraisal to their workers. These typically are computer-processed analyses of the risk of death for a member of a given age or sex cohort likely to result from such deleterious "lifestyle" behaviors as inadequate exercise, poor nutrition, smoking, and excessive alcohol consumption.

As with screening programs, only a comparatively low percentage sponsor intervention programs which are intended to promote health or prevent disease. Again, larger firms are more likely to offer disease prevention and health promotion programs than are smaller firms. Between 14 and 26 per cent of the respondents either directly or indirectly provide programs in first aid, cardiopulmonary resuscitation, accident prevention, and the Heimlich maneuver. Some of the more commonly-sponsored programs such as first aid instruction and accident prevention address major occupational health problems. Programs targeted toward cardiopulmonary resuscitation and the Heimlich maneuver may be offered more frequently because they are readily available to interested sponsors. Only four per cent of the respondents sponsor activities which attempt to modify such difficult behavioral problems as smoking, lack of exercise, and weight control.

Table 2. — Firms with Organized Health Promotion Activities

Firm Size	Number with Program	Number of Responses	Per Cent
20-49	12	196	6.12
50-99	10	54	18.52
100 or more	68	280	24.28
Total	90	530	16.98

Firms also were queried as to the benefits of health promotion programs to both employers and their employees. Table 5 indicates that a significant percentage of the respondents attribute valuable benefits to health promotion programs. While the most commonly-cited one is "better health information," a majority of the firms also correlate health promotion programs with a reduced risk of disease, less absenteeism, fewer compensation claims, and improved employee morale. Moreover, more than 40 per cent of the respondents believe that health promotion programs increase worker productivity, reduce health and life insurance claims, and reduce premiums for worker's compensation, short-term disability insurance, and health insurance. Finally, firms with 100 or more employees perceive more substantial benefits from these programs than do smaller companies.

The Rhode Island experience seems to resemble worksite programs in at least one other state. In one of the few published reports to date, Fielding and Breslow recently addressed the findings of their 1981 survey of health promotion activities sponsored by California employers with 100 or more workers.⁷ As in Rhode Island, the larger firms were more likely to sponsor an identifiable activity. Approximately 98 per cent of the California firms with 5,000 or more employees had implemented at least one program compared to 66 per cent of the companies employing 100-249 workers. General programming trends appear to be similar in both states. While programs on accident prevention, cardiopulmonary resuscitation, and the Heimlich maneuver were the most fre-

Table 3. — Testing and Screening Programs By Size of Firm

Program	Number of Employees			Total
	20-49 Employees	50-99 Employees	100 or More Employees	
Breast cancer	2 (1.02)*	0 (0)	20 (7.86)	22 (4.53)
Pap smear	3 (1.53)	0 (0)	6 (2.14)	9 (1.70)
Lung function	3 (1.53)	1 (1.85)	15 (5.36)	19 (3.50)
Hypertension	5 (2.55)	2 (3.70)	68 (24.29)	75 (14.16)
Diabetes	2 (1.02)	0 (0)	23 (8.21)	25 (4.72)
Glaucoma	2 (1.02)	1 (1.85)	22 (7.86)	25 (4.72)
Tuberculosis	8 (4.08)	3 (5.55)	33 (11.79)	44 (8.30)
Physical Examination	17 (8.67)	10 (18.52)	66 (23.57)	93 (17.55)
Health Risk Appraisal	1 (0.51)	0 (0)	16 (5.71)	17 (3.21)

* Parenthetical number indicates percentage of responding firms.

Table 4. — Intervention Program Data

Program	Number of Employees			Total
	20-49 Employees	50-99 Employees	100 or More Employees	
Weight Control	2 (1.02)*	4 (7.40)	23 (8.21)	29 (5.47)
Physical Fitness	2 (1.02)	2 (3.77)	16 (5.71)	20 (3.77)
Nutrition	2 (1.02)	2 (3.70)	17 (6.07)	21 (3.96)
Smoking Cessation	3 (1.52)	2 (3.70)	18 (6.43)	23 (4.34)
Alcohol/Drug Abuse	3 (1.53)	2 (3.70)	40 (14.28)	75 (8.49)
Stress	4 (2.04)	3 (5.55)	11 (3.93)	18 (3.40)
Personal Health	3 (1.53)	1 (1.85)	26 (9.29)	30 (5.66)
First Aid	18 (9.18)	5 (9.26)	116 (41.43)	139 (26.23)
Self Protection	10 (5.10)	6 (11.11)	41 (14.64)	57 (10.75)
Accident Prevention	15 (7.65)	10 (18.52)	91 (32.50)	116 (21.89)
Back Pain Prevention	8 (4.08)	3 (5.55)	44 (15.71)	55 (10.38)
CPR	13 (6.63)	6 (11.11)	97 (34.64)	116 (21.89)
Heimlich Maneuver	15 (7.65)	6 (11.11)	76 (27.14)	97 (18.30)
Preventive Dental	6 (3.06)	1 (1.85)	9 (3.21)	16 (3.02)
Health Education	4 (2.05)	2 (3.70)	30 (10.71)	36 (6.79)
Health Insurance Covering Preventive Services	21 (10.71)	6 (11.11)	48 (17.14)	75 (14.15)

* Parenthetical number indicate percentage of responding firms.

Table 5. — Perceived Benefits of Health Promotion Programs

	Number of Employees		
	20-49 Employees	50-99 Employees	100 or More Employees
Reduces Disease Risk	88 (44.89)*	29 (53.70)	173 (61.78)
Reduces Absenteeism	88 (42.86)	24 (44.44)	186 (66.43)
Reduces Comp Claims	72 (36.73)	22 (40.74)	171 (61.07)
Reduces Health Life Insurance Claims	66 (33.67)	19 (35.18)	151 (53.93)
Provides General Information	96 (48.97)	31 (33.33)	200 (71.43)
Improves Productivity	63 (32.14)	18 (33.33)	146 (52.14)
Improves Morale	81 (41.33)	22 (40.74)	174 (67.79)
Lowers Premiums	67 (34.18)	19 (35.18)	166 (59.28)

* Number (per cent of respondents).

quently offered activities in both states, comparatively few employers in either California or Rhode Island developed programs on such behavioral issues as smoking, weight control, nutrition, and fitness.

Discussion

There appears to be a direct relationship between the size of the firm and the existence of employer-sponsored health promotion activities. In Rhode Island, the larger firms surveyed (ie, 100 or more employees) were approximately four times as likely to offer such programs as the smallest firms (ie, 20-49 employees). Because most persons are employed by comparatively small organizations, these findings suggest that it may be difficult to reach a significant portion of the adult working population through worksite health promotion programming.

With the exception of programs directed toward accident prevention, cardiopulmonary resuscitation, and the Heimlich maneuver, few employers sponsor activities designed to address specific health problems. Accident prevention programs are required by law for many employers, and training in both cardiopulmonary resuscitation and the Heimlich maneuver is readily available from voluntary health agencies. Few employers sponsor health promotion programs intended to reduce such major risk factors as smoking, poor nutrition, lack of exercise, substance abuse, and hypertension. If the findings accurately reflect the sentiments of the Rhode Island business community, however, there is reason for optimism concerning the future of worksite programming. Regardless of the firm size, important benefits were perceived as resulting from these programs. Most employers believe that health promotion programs reduce the incidence of disease, absenteeism, and compensation claims and improve employee morale. More than 40 per cent of the respondents also felt that health promotion programs would increase employee productivity, reduce health and life insur-

ance claims, and lower premiums for workers' compensation, short-term disability, and health insurance.

To stimulate the widespread adoption of such activities, however, a varied approach may well be necessary. Public health agencies, voluntary organizations, and commercial underwriters of risk reduction programs should develop cost-effective educational programs which address major risk factors. The providers of risk reduction programs might encourage more firms to sponsor such activities if they were to offer more comprehensive service packages, including employee solicitation, integrated management support services, a range of risk reduction programs, and evaluation services. Finally, greater public subsidy and broader coverage of health education activities than currently available under most medical insurance programs would contribute substantially to increasing the number of worksite programs.

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SPECIAL REPORT

Rhode Island General Assembly Adjourns in May

Elizabeth Conklin

After a last-minute deadlock over the state's budget, the Rhode Island General Assembly adjourned for the year on May 11, 1984, almost a week later than scheduled. During the three-month long session, the lawmakers considered nearly 200 bills on health-related matters. After reviewing these proposals, the Public Laws Committee, under the leadership of Doctor Peter D. T. Clarisse, recommended that the Society target its efforts on 40 bills through testimony and lobbying. The daily monitoring of legislative activities by Society staff, according to Doctor Clarisse, also contributed substantially to the "success of this year's efforts."

The following major issues emerged during the 1984 session:

Medical malpractice: At the request of the Society, Senator John Revens (D, Warwick) sponsored a package of five bills intended to alleviate the malpractice crisis. The bills, if passed, would have established guidelines for the structured payment of awards greater than \$100,000, reduced the interest on awards from 12 per cent to 10 per cent, and limited awards for pain and suffering to \$250,000. An amendment to the collateral source rule and the establishment of qualifications for expert witnesses were also included in the proposed legislation.

Instead of acting on the original malpractice package, the Senate Judiciary Committee created a special legislative commission to study the problem and report its findings by next February. The

15-member commission is to include one representative each from the Rhode Island Medical Society and the Joint Underwriting Association.

The General Assembly also considered several proposals regarding the statute of limitations. A new law covers injuries resulting from alleged malpractice which were not discoverable at the time of occurrence. For such cases, the plaintiff may file suit within three years of the date the injury should have been discovered instead of the previous three-year limitation dating from the occurrence of the incident. Another recently-enacted law extends the period for suing a deceased person from one year after the death until one year after the appointment of an executor.

The escalating malpractice problem, Doctor Clarisse told the annual session of the House of Delegates in May, will continue as "the Society's major priority" during the 1985 session.

Optometric drug use: As the result of combined efforts by the Society, the Rhode Island Ophthalmological Society and the Brown University Program in Medicine, the House Corporations Committee refused to act on a bill which would have permitted optometrists to use therapeutic drugs to treat ocular disease. While optometrists in 37 states, including Rhode Island, may use drugs for diagnostic purposes, prescription of therapeutic agents is permitted only in West Virginia and North Carolina.

Doctor Milton W. Hamolsky, Physician-in-Chief, Department of Medicine, Rhode Island Hospital, and RIMS Secretary, told the legislators that many ocular conditions may be manifestations of general systemic disease which optometrists are not trained to recognize. Also speaking against the bill were Doctors David S. Greer, Dean, Brown University Program in Medicine; Robert S. L. Kinder, Chief of Ophthalmology, Rhode Island Hospital; H. Demman Scott, Director, Rhode Island Department of Health; Thomas Hutchinson, Harvard Medical School; and Alfred Lemoine, a Kansas City

Elizabeth Conklin currently is enrolled in the Post Baccalaureate Premedical Program, Bryn Mawr College, Bryn Mawr, Pennsylvania. After Brian R. Clarke left the Society in April to accept a position with Blue Cross & Blue Shield of Rhode Island, Ms. Conklin was engaged to monitor legislative activities for the Society during the last two months of the 1984 session.

ophthalmologist.

The successful legislative strategy was organized by Doctor Y. Jacob Schinazi, President, Rhode Island Ophthalmological Society.

Physicians assistants (PAs) and allied health providers: The 1984 session saw more attempts by non-physician health care providers to expand their clinical role through legislation. The House Health, Education, and Welfare (HEW) Committee considered two bills which, if approved, would have expanded the scope of practice of PAs. In testimony before the House HEW Committee, then RIMS President Doctor Charles P. Shoemaker supported a bill introduced by Brown University which would have exempted PAs in university settings from the supervision requirements of the current PA law. Approved by the Committee, this bill later was amended on the House floor to include the broader provisions of a second bill which had been rejected earlier by the House HEW Committee. Doctors Shoemaker and Charles E. Millard, a RIMS past president (1981-1982), emphasized before the Senate HEW Committee the dangers of "expanding the scope of practice by legislative fiat rather than through education and training." They also pointed out some of the many inconsistencies which have resulted from the proliferation of separate licensing boards for each of the allied health professions. As the result of growing opposition, the Senate HEW Committee refused to act on the PA proposal, and the bill died for the year.

The General Assembly, however, did enact several bills which affect allied health providers. The Rhode Island Department of Health has been authorized to create a licensing board for occupational therapists. Legislation also was approved which establishes standards for clinical social workers and provides a licensure mechanism through the Rhode Island Department of Social and Rehabilitative Services. The lawmakers reduced the total period of clinical training for athletic trainers from 1,800 to 1,000 hours. As the result of opposition from the Society and other organizations, a bill to license "marital and family therapists" was defeated.

Living wills: Representing both the Society and the Rhode Island District Branch of the American Psychiatric Association, Doctor James R. McCartney testified before the Senate Judiciary Committee in support of a bill which would have provided a voluntary mechanism for living wills. While the bill was defeated on the Senate floor, the General Assembly did create a special legisla-

tive commission to study the right of "adult persons to control decisions relating to their medical care."

Mental health: Both the House and the Senate considered several proposals which would have eliminated "mental injury" as a compensable expense under the worker's compensation program. While the Society, in cooperation with the Rhode Island District Branch of the American Psychiatric Association, successfully sought an amendment to provide compensation for diagnosed psychiatric disabilities, no action was taken on either the original or amended versions.

Worker's compensation: As part of the legislative debate over the Greenhouse Compact proposals, the Rhode Island General Assembly considered several bills designed to reform the worker's compensation system. Doctor Anthony F. Merlino testified before the Senate Finance Committee in opposition to a bill which would have mandated that all rehabilitative services for worker's compensation cases be performed by the John Donley Center in Providence. While the Senate bill failed, two House bills with similar requirements later surfaced during the session. Under the law finally approved by the General Assembly, an employer may petition to have the Donley Center evaluate the rehabilitative services provided to an injured worker by other providers.

Legal drinking age: In testimony before the Senate Special Legislation Committee, Doctors Shoemaker and John S. O'Shea strongly supported a move to increase the state's legal drinking age to 21 years. The new law became effective July 1.

Emergency telephone system: Doctor Jack B. Franaszek, representing both the Society and the Rhode Island Chapter of the American College of Emergency Physicians, told the Senate HEW and Finance Committees that a 911 emergency number system is essential to providing adequate emergency services. The General Assembly authorized placing a \$5 million bond referendum to finance implementation of a 911 system on the November ballot.

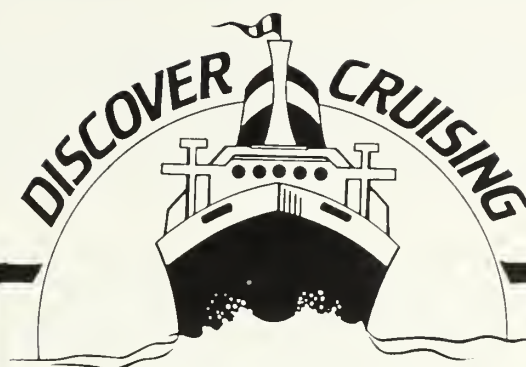
Limited licensure: In an action long supported by the Society, the General Assembly approved a bill which extends the authority of the Board of Medical Review to cover physicians with limited licenses.

Physicians participation in insurance programs: Several pieces of legislation were introduced in a continuing effort to require that physicians disclose more information concerning their billing policies. Early in the session, the House approved

a resolution calling upon Congress to mandate acceptance of Medicare benefits as "payment in full."

Dr. Augustine McNamee testified against a bill which would have required anesthesiologists to inform their patients if services are covered by insurance before any procedures are performed. Because of the way that many anesthesiology departments are organized, Doctor McNamee said this provision would be "unworkable." While the House HEW Committee refused to act on this bill, the General Assembly did enact legislation which requires physicians to disclose their Medicare assignment policy concerning office procedures. This act also mandates that all health care facilities provide patients with a summarized medical bill upon discharge.

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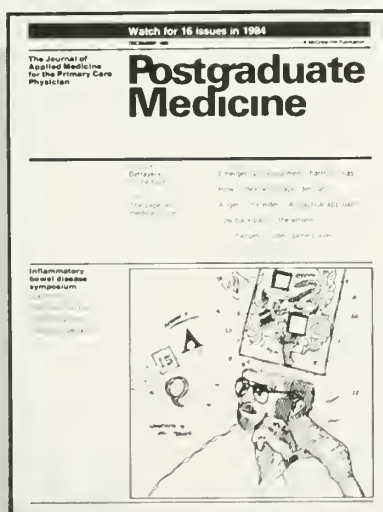
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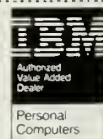
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1984 ANNUAL MEETING REPORT

Committee Reports

The following reports of committee activities during 1983-1984 were submitted for the consideration of the House of Delegates at its May 23, 1984 annual session:

Committee on Aging

The Committee on Aging met twice during 1983-1984 under the leadership of its chairman, the late Doctor Johannes Virks, to discuss the following:

Educational activities on geriatrics: The Committee met with Doctor Marsha Fretwell, Assistant Professor of Medicine, Brown University Program in Medicine, and Head, Section on Geriatrics, Roger Williams General Hospital, to discuss the medical school's activities in this area.

Outpatient Geriatric Assessment Unit: At the time of his death in March 1984, Doctor Virks was head of an outpatient geriatric assessment unit at the General Hospital, Rhode Island Medical Center. The Committee had discussed the project at both its meetings. The unit was developed to provide integrated medical, psychiatric, and psychological assessments of elderly patients referred by private physicians and service agencies.

Nursing homes: At its May 17, 1983 meeting, the Committee met with 15 medical directors of Rhode Island nursing homes to discuss issues related to long-term care.

In addition, Committee members represented the Society at the following legislative hearings: 1) Doctor Marsha Fretwell represented RIMS before the Rhode Island General Assembly Home Health Care Committee in February 1984. The legislative committee is charged with expanding the provision of home health services to Rhode Island citizens; 2) Doctor Henry Izeman testified at a special April 1984 session of the US House Committee on Aging sponsored by Rep Claudine Schneider in Warwick. Doctor Izeman participated as part of a panel which also included representatives from the Hospital Association of Rhode Island and Health Care Review, Inc; and

3) The Society also was represented at a June 16, 1984 program on Medicare organized by the office of Senator Claiborne Pell. Nearly 1,000 senior citizens participated in the day-long meeting held at the Community College of Rhode Island in Warwick.

Cancer Committee

The Cancer Committee has been active during the past year in supporting the development of a computerized statewide tumor registry. A meeting was held November 1, 1983 to encourage the participation of physicians in the development of the registry, which is being coordinated through the Hospital Association of Rhode Island (HARI).

Representatives of the 16 general hospitals in Rhode Island were invited to discuss the background of the tumor registry system in the state and to plan for hospital and physician involvement in the continued activity of a computerized system for the collection of important data on newly-diagnosed cancer cases and follow-up survival information. The Cancer Committee had previously endorsed the development and approval of cancer programs and registries under the protocol developed by the American College of Surgeons. After the Committee's November meeting, the HARI Cancer Program Council expanded its physician membership. The Cancer Committee also plans to encourage hospital coordination between the liaison members of the American College of Surgeons with Committee members to facilitate the development and approval of hospital cancer programs approved by the College.

The Cancer Committee also has endorsed programs dealing with cancer and the elderly as well as the many active educational programs and tumor boards throughout the state.

Francis J. Cummings, MD
Chairman

Educational and Scientific Board

The Educational and Scientific Board is responsible for maintaining the Society's authorization to award credit for continuing medical education programs from the Accreditation Council for Continuing Medical Education. Nine hospitals in Rhode Island currently receive their authorization to review programs for Category 1 CME credit from the Society.

As part of its continuing activities, the Board also reviews applications for CME credit from other program sponsors, including pharmaceutical companies and state specialty organizations. This is a responsibility that the Board regards as an especially serious one since the awarding of CME credit carries with it the imprimatur of the Rhode Island Medical Society as a co-sponsor.

During the past year, the Board has approved nearly 40 applications for CME credit from pharmaceutical houses, the Rhode Island Department of Health, and state specialty organizations. A member of the Educational and Scientific Board routinely attends many of these programs to assure their educational value.

Edward A. Iannuccilli, MD
Chairman

Library Committee

The major goal of the Library Committee during the past year has been weeding the Library's collection. The objective of the weeding project is to maintain a library collection of unique, rare, or historically important material and a small, representative section of current clinical information. To date, 14 of the 42 major subject areas have been weeded with invaluable assistance from individual Society members.

The Library continues to provide reference services and materials from the collection to Society members and the general public. Statistics for the period June 1983 to May 1984 include: 1) interlibrary loan transactions: 775 articles (529 for members); 2) materials provided directly from the collection: 454 articles and 49 books; and 3) visits: 133 members and 332 others, including health care professionals, students, and general public. Eighty-three books were added to the library collection and 183 journals are currently being received, 30 by subscription and 153 on a gift or exchange basis. The Library is expanding its collection of socio-economic and statistical material. Publications of the American Medical Association, including all legislative

analyses and statistical reports, also are maintained on file.

The Library Committee has established the following goals for 1984-1985: continuation of the weeding project, maintenance and preservation of the collection, and additional publicity concerning the Library and its services.

Jay M. Orson, MD
Chairman

Committee on the Medical Aspects of Sports

The Committee on the Medical Aspects of Sports has decided not to hold a national meeting at the University of Rhode Island during 1984. The Committee currently is considering sponsorship of a joint meeting with another organization on the value of exercise as a component of weight reduction.

A. A. Savastano, MD
Chairman

Medical Economics Committee

The Medical Economics Committee met August 26, 1983. The issue of whether hospitals can require its staff members to retain malpractice insurance was discussed. After considerable research concerning such policies in Rhode Island and elsewhere, it was determined that there is considerable support for such policies. In fact, the courts already have determined that hospitals are well within their rights to establish this requirement as a condition for staff membership.

The issue of indemnity versus usual, customary and reasonable systems of reimbursement was discussed. The committee took no position on this subject, but developed an informational report for the consideration of the House of Delegates.

The committee chairman also met with a private insurance company consultant to investigate the feasibility of encouraging a return of private insurance carriers to the state for the purpose of underwriting malpractice insurance.

Louis Vito, Jr., MD
Chairman

Joint Medical-Legal Committee with Rhode Island Bar Association

In May 1983, then Society President Doctor Melvin D. Hoffman, with the agreement of the then President of the Rhode Island Bar Association, Melvin Chernick, reactivated the Joint Medical-

Legal Committee. Representatives from each organization were appointed. The Committee was established to review, discuss, and, if possible, develop a consensus regarding mutual problems. The initial representatives from the Society included Doctors Paul T. Welch, Edward Spindell, Robert J. Westlake, Charles J. Ashworth, Jr., and Royal C. Hudson. The initial members from the bar association were Thomas D. Gidley, E. Paul Grimm, Richard P. McMahon, Ira L. Schreiber, Ralph B. Semanoff, and Merrill W. Sherman. During the year, Doctors Hudson and Ashworth resigned and Doctors Elie J. Cohen and Leonard F. Hubbard were appointed in their place.

A total of ten meetings were held between June 1983 and May 1984. The Joint Committee elected a chairman from one organization and a secretary from the other for the year. Thomas D. Gidley was elected chairman and Brian R. Clarke, then Assistant Executive Director of the Society, provided staff support during the year. The Committee, in addition to its consideration of mutual concerns, also was charged with reviewing legislative proposals which affect the two professions. The following issues were considered: confidentiality, "do not resuscitate" orders, medical/legal cooperation code, interprofessional code, and the release of medical records.

Proposed topics for 1984-1985 will be further consideration of the revised interprofessional code, a review of the medical malpractice liability problem, further deliberation concerning "do not resuscitate" regulations which may be promulgated through the Medical Examiners Commission, and technological advances and legal problems.

The interprofessional code deliberations have met with diverse opinions which are, as yet, unresolved. As a result, a new code has not emerged for the consideration of both organizations. Further work through dialogue and compromise are required on the issues of the interprofessional code and the release of medical records.

The Joint Committee has met faithfully with lively conversation, free exchange of viewpoints, and the respectful consideration of opinions held by our colleagues. I look forward to submitting an interprofessional code that will be satisfactory to both professions in the near future with the inspired input from Ira Schreiber as co-author. I anticipate the development of uniform regulations for all Rhode Island hospitals for "do not resuscitate" orders within the next year. Doctor Westlake will undertake additional consideration of the confidentiality of medical records and the

appropriate appointment of guardians for the incompetent. It has been a year of excellent exchange of attitudes and ideas between the two professions. The results of this Joint Committee should be productive and benefit both physicians and attorneys.

Paul T. Welch, MD

Mental Health Committee

The Mental Health Committee had no new business to consider during 1983-1984 and did not hold any meetings. The Rhode Island District Branch of the American Psychiatric Association has been active in most of the areas that previously concerned this committee.

Louis V. Sorrentino, MD
Chairman

Professional Health Care Providers Committee

In January 1983, the Committee reassessed its approach of the previous two years in establishing dialogues with various allied health provider organizations. After much deliberation, the Committee decided to continue asking representatives of these various organizations to present a synopsis of their particular field and of their perceptions of how the Society could interact most effectively with their organizations. After another planning meeting in February 1983, the Committee met with Doctor Brian Hayden, President, Rhode Island Psychological Association, in April 1983; and with Robert O'Brien, President, Rhode Island Chapter, American Physical Therapy Association in April 1984. The Committee plans to meet in May 1984 with Robert Treichler, Rhode Island Chapter, Association of Hospital Social Work Directors; and in June 1984, with Barbara Sherman and Judy Shehan of the Rhode Island State Nurses Association.

In September and November 1983, the Committee also considered proposed guidelines on legislative proposals affecting allied health personnel. The Committee also helped in clarifying various issues pertaining to the registration of physician's assistants.

Members of the Committee include Doctors Marisse Allegra, Salvatore G. Azzoli, Ronald Cavanaugh, Joseph H. Delfino, Allan A. DeSimone, Walter R. Durkin, Norbert Fleisig, Patri-

cia Hyzinski, Raymond E. Moffitt, and John S. O'Shea.

John S. O'Shea, MD
Chairman

Publications Committee

The Publications Committee is charged with the "publication and distribution of the Society's official journal." During the past year, the Committee met three times to review the following:

Production costs: The Committee authorized renewing the contract for printing and distributing the *Rhode Island Medical Journal* with The Ovid Bell Press, Inc., Fulton, Missouri. The Press specializes in printing publications with a small-to-medium sized circulation base, and considerable cost savings have resulted from their expertise in this area. The Committee also authorized the use of a different type of binding which will result in an additional cost savings during the next year.

The Committee met with John Bell in October 1983 to review the contract and analyze the impact of technological innovations at The Ovid Bell Press, Inc. on the *Journal*. Several new systems have been installed which should reduce production time.

Advertising income: The *Rhode Island Medical Journal* derives its advertising revenue from two sources, the State Medical Journal Advertising Bureau (SMJAB) and local advertising solicited by RIMS staff. Doctor Seebert J. Goldowsky, Editor-in-Chief, serves on the SMJAB Board of Trustees. As a reflection of a national trend, the number of advertisements placed by SMJAB in the *Journal* declined by 14 per cent in 1983. SMJAB recently changed advertising representatives and preliminary figures for 1984 indicate that the receipts from national advertising should increase during the next year. The loss of income from SMJAB advertisements, however, has been partially offset through an aggressive advertising campaign undertaken by RIMS staff. During the past year, solicitation letters have been sent to more than 500 prospective advertisers. As a re-

sult of this effort, the advertising revenues from local companies have increased by nearly 40 per cent over the past year.

Coverage of social, legislative, and economic issues: The *Journal* has expanded its coverage of social, legislative, and economic issues of interest to all Rhode Island physicians.

Editorial impact: During the past year, a *Journal* editorial received national exposure. The October 1983 editorial, "Hospital for Sale," was quoted in *American Medical News* as an example of the regional reaction to a proposed sale of McLean Hospital by the Harvard Medical School. The Publications Committee believes that this reference is especially noteworthy in view of the comparatively small circulation of the *Journal*.

Guy A. Settipane, MD
Chairman

Committee on Occupational Health

The major goals of the Committee on Occupational Health are to enhance the education of physicians concerning occupational problems and to increase communication among physicians who treat occupationally-related illnesses. Two major programs will be presented to the Committee at its June 1984 meeting. The first task will be to develop a series of topics concerning the diagnosis, prevention, and treatment of occupationally-related illness, and to write short summaries of these problems which will have practical value to the physicians faced with these illnesses in their offices. It is to be hoped that some of these summaries will be published in the *Rhode Island Medical Journal*. The second task will be the development of a resource list to provide information concerning the services available for the prevention and evaluation of occupationally-related illnesses and laboratories which have a special interest in occupational problems.

Michael A. Passero, MD
Chairman

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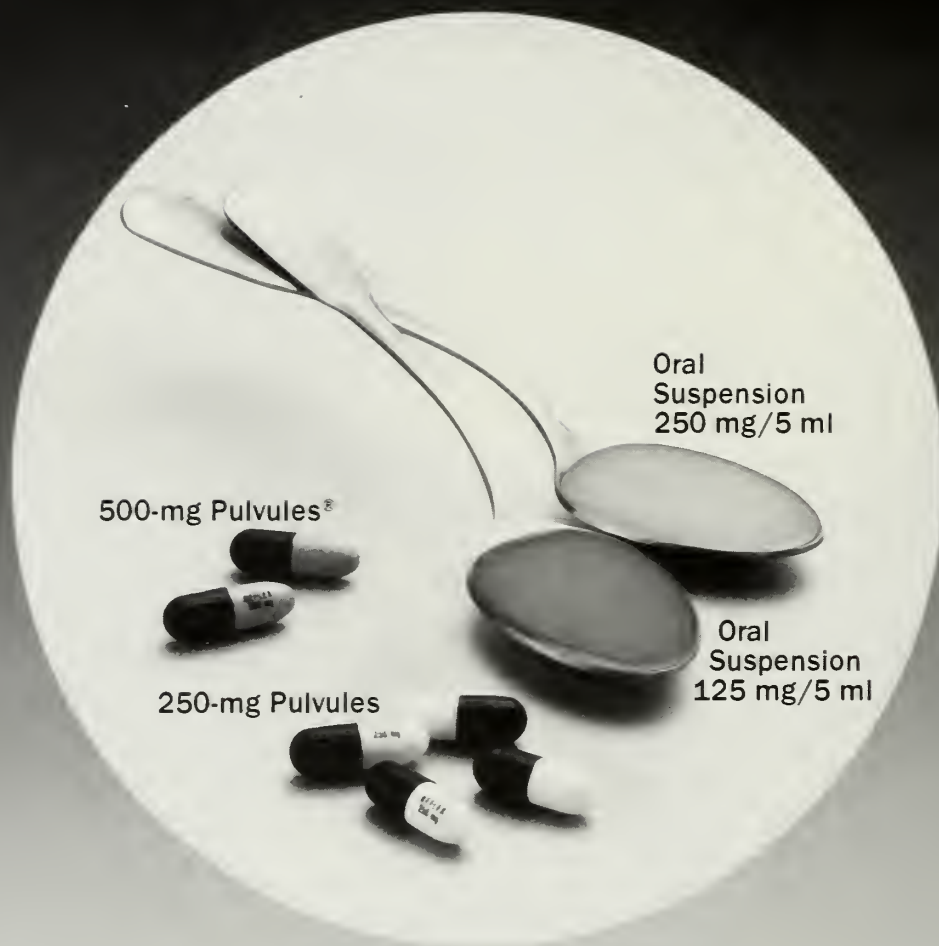
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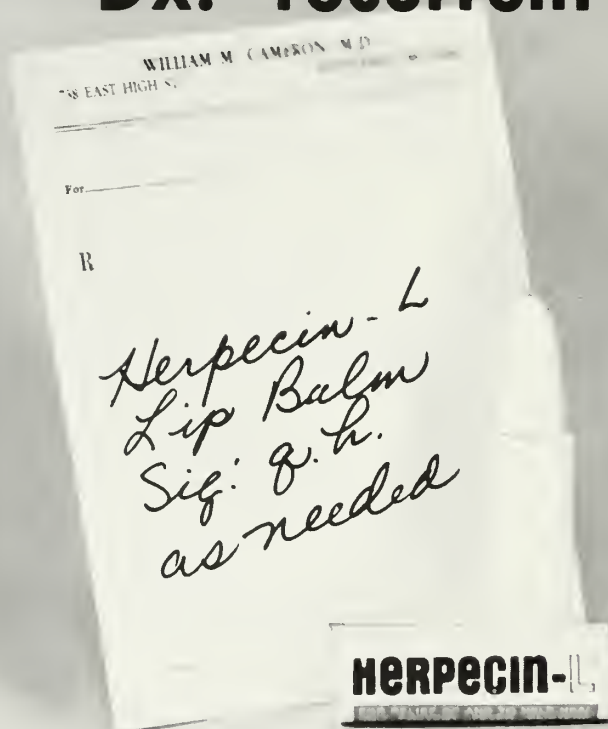
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1984 ANNUAL MEETING REPORT

Report of the Executive Director

Norman A. Baxter, PhD

At the request of Doctor Charles P. Shoemaker, Jr., President of the Rhode Island Medical Society, I am pleased to present a supplement to his annual report being made today to the House of Delegates and to this annual session of the Society.* As the executive officer charged with the continuing management of the Society, my perspective may offer some additional insights into the Society's role and task.

At the outset, let me say that the Society has benefited greatly this year, as in other years, from the unstinting efforts of both officers and staff. Working diligently on several fronts, there are many solid achievements to point to and take pride in.

The more obvious ones come to mind first:

Publication of the *Guide to Physician Services* in early April was a highlight of the year. Conceived by the late Doctor Melvin D. Hoffman in response to public interest groups, the *Guide* was only the second such statewide directory in the United States. The reception to it has been strongly positive because it shows clearly that RIMS members are willing to have their credentials and qualifications open to the public. It is a giant step forward in strengthening public confidence in the medical profession.

The exact results of a very effective legislative session are presented in a report of the Public Laws Committee, chaired by Doctor Peter D. T. Clarisse. The results, while impressive and important, were accompanied by several developments. First was the close cooperation with one of the specialty societies, the Rhode Island Ophthalmological Society. A united front was presented in testimony before the House Corporations Committee and was effective in defeating a bill which would have allowed optometrists to use

therapeutic drugs. Second was the initiative seized by Doctor Paul J. M. Healey, President-Elect, in having tort reform legislation drafted by our legal counsel, Edwards & Angell, and introduced in five bills in the Senate. The outcome of this was a special legislative committee to study the malpractice problem in Rhode Island and to propose remedial legislation. Third, we developed a closer liaison with Brown University and with the Rhode Island Department of Health than in the past.

The Society is very visible and well identified at the State House, a posture we intend to enhance in the future because so many bills are introduced each session which impinge, directly or indirectly, on the quality and practice of medicine.

Testimony before the Joint Underwriting Association (JUA) in June 1983 concerned increases in malpractice insurance rates. The requested 64 per cent increase was pared down to 24 per cent in large part because of the testimony presented by the actuary engaged by the Society. This saves doctors and hence patients thousands of dollars. A full report on this hearing, including the arguments of our actuary, was printed in the August 1983 issue of the *Rhode Island Medical Journal*.

Establishment of the RIMS Foundation: Almost a year ago, the Society requested and received a 501.c.3. status from the Internal Revenue Service for a charitable foundation to provide a vehicle for the Society members to contribute to projects and advance medical causes and interests and at the same time receive a tax deduction for their contribution. At the present time, the RIMS Foundation, under the leadership of Doctor Paul J. M. Healey, is planning to solicit contributions from those who benefit from a distribution of proceeds of the *Barry* case. Such funds would be designated for projects associated with tort reform, a very logical and reasonable use since the funds originated from an award made because of

* Shoemaker CP, Jr: The Year in Review. *RI Med J* 67(5):217, 1984.

a lawsuit filed by Doctor Healey and others concerning malpractice insurance.

Throughout the year, my third with the Society, I have been impressed by the number of ways the Society's influence is felt and its counsel and input are sought. I am equally pleased to report that this circle and sphere of influence seems to be widening. As you might expect, our contacts are most frequent with the Rhode Island Department of Health, Hospital Association of Rhode Island, Blue Cross & Blue Shield of Rhode Island, and SEARCH. Yet, contacts with Brown, the Joint Underwriting Association, Health Planning Council, and public agencies such as the Department of Elderly Affairs also are increasing and absorb more staff time and research.

Future Trends and Directions

I would like now to identify some trends and directions which I see developing on the horizon.

This past year a physician was disciplined by the Board of Medical Review. The physician asked his local society to review the procedures utilized by the Board and in turn the local society asked RIMS for aid. Then president Doctor Shoemaker appointed a committee of three physicians and the Society's legal counsel to look into the matter. Their report is not yet available, but the incident itself is significant. The physician often needs an advocate because threats may come from many sources and emerge in a variety of ways. It may be that the Society will need to play the advocacy role more frequently in the future, not to decide who is right and wrong, but was the matter fairly and properly handled. This is a very sensitive area which needs more attention and thought, but one which, I suspect, the Society will face with increasing frequency.

The other trend is more easily described. We need a *legislative network*. By that I mean a current list of doctors throughout the state who are in close contact with legislators in their areas. At a given time during the legislative session, these doctors can be called upon to visit their legislator to make the Society's views known. As I have witnessed legislative hearings and talked with legislators directly, they seek information, more than direction, in order to make informed judgments. They want to know what the Society, or any other group, thinks. We fail them and ourselves if we do not provide information. We must identify doctors with such legislative contacts in order to be a responsible society. Such a network is the first requirement for an effective legislative program. We simply must be able to

transmit effectively our collective wisdom on matters affecting the profession.

The question of medical manpower has been before the Society off and on for several years and was a part of the relicensure survey in 1980. The results of that survey were somewhat unclear and the late Doctor Paul Metcalf set about to clarify the issue, but he died before completing his work. The data the Rhode Island Department of Health presented at the meeting of the House of Delegates in January 1984 is four years old. Brown University periodically announces additional faculty appointments to staff new or enlarged residency training programs, adding to the changing and complex picture of medical manpower. Currently, the Brown Liaison Committee of the Society is addressing the issue. We are very interested in the outcome of this to see what light it will shed on the "physician glut" and what the future looks like for medical manpower in Rhode Island.

Society Membership

For many years, RIMS membership has been stable, despite a larger than average number of physician members older than 60 years of age. For the fourth consecutive year, the Society has received an award from the American Medical Association for increasing its AMA membership. The time is certainly here for a concentrated effort to contact physicians who are coming into Rhode Island and invite them to join the Society. I am very pleased to report that Doctor Frances Conklin, President, Providence Medical Association, is planning to meet on June 22 with new residents at their orientation session and talk to them about the importance of the Providence Medical Association and the Rhode Island Medical Society. We need more efforts in this regard if we are to increase our membership significantly. Membership, needless to say, is the source of our influence and financial strength.

Administrative Activities

Lastly, I should like to report on a series of activities during the year which reflect progress and accomplishment in the housekeeping side of the Society.

After several unsuccessful efforts to sell the property at 9-11 Hayes Street, the Council authorized RIMS to form a general partnership and sell the building, but not the land, to the general partner, Hayes Street Associates. The building is now being renovated for offices and will be ready for occupancy this fall. The Society will receive

\$3,500 annually in ground rent and will retain title to the land. The land is becoming more valuable because of the Capitol Center project and by retaining the land, the Society has added to its long-term financial stability.

The Society's building at 106 Francis Street was upgraded this year by a new roof. Work was performed in the auditorium to repair the damage from a leaky roof, and the brick and stone work on top of the building were repointed and sealed. These repairs, in addition to the work completed during the past two years, have put the building in excellent condition.

In November 1983, the Medical Bureau closed, thus ending our rental income of nearly \$10,000 each year. This creates a serious cash flow problem for us in the 1984 fiscal year, but for 1983 the financial condition of the Society was excellent, as the Report of the Treasurer and the certified financial statement from the auditor both indicate.

The local advertising revenue of the *Rhode Island Medical Journal* has increased nearly 40 per cent, thanks to the efforts of Wendy Smith, Managing Editor. This increase helps offset the decline in national advertising which is occurring with all state medical journals. The local increase

is certainly healthy, indicating local readership and confidence in the *Journal* by local business leaders.

During the year we have had three staff changes. In September, Edwina Rego joined us as our receptionist, and also that month, Marion Sabella was appointed as our librarian. Marion received her MLS degree this month from the University of Rhode Island. In April 1984, Brian Clarke left the Society to take a position with Blue Cross & Blue Shield of Rhode Island. He is being replaced in June by Newell E. Warde, PhD, who has been on the Bates College faculty for seven years. We welcome these new staff members as they add to our effectiveness and help us to make the Society the fine place it is.

I should like to express my appreciation to Doctor Shoemaker for his leadership this past year. He has made himself available to us as needed and his counsel and insights have greatly strengthened the Society. I extend my appreciation to all our staff because it is through their hard work and dedication that the Society is able to move forward in discharging its charter responsibility "to promote the art and science of medicine."

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LETTER TO THE EDITOR

Certificate-of-Need Process Defended

To the editor:

I am writing in response to the editorial in the March 1984 issue of the *Rhode Island Medical Journal*. The subject of that editorial was the potential contribution that voluntary health planning can offer toward developing a more competitive and innovative health care system, as opposed to the current limited regulatory approach, specifically certificate-of-need requirements. As support for this position, the editorial referred to computerized tomography (CT) equipment.

I feel compelled to respond to certain criticisms of the certificate-of-need (CON) program raised in that editorial. As points of clarification: (1) The initial Health Services Council policy to allocate this high technology equipment conservatively was based on the recommendations of a statewide planning study performed by a credible voluntary health planning agency with significant professional input; (2) Control over the initial placement of this equipment in Rhode Island and elsewhere was justified because, at that time, the clinical efficacy of CT was not fully determined; (3) This planned, conservative approach to allocation has resulted in Rhode Island hospitals acquiring more advanced CT scanners (3rd and 4th generations) whereas other communities with more liberal approaches installed more limited first and second generation equipment; (4) The equipment is not "available virtually everywhere," but allocations have been made to seven of the fourteen general community hospitals

based on adequate determinations of public need, cost analysis, clinical and financial feasibility.

Also, with reference to the broader issue of planning and CON, I must point out that given the present perceived linkage between rising health care costs and high technology, health care policy makers would be derelict in the discharge of their public trust if they were to approve new and expensive technologies in the absence of some form of a rational plan for proposed services. Given the reality of limited resources, the particular economics of health care, and the apparent inability of providers to plan together for more efficient allocations, such decisions will, by necessity, result in some explicit form of rationing.

I hope that the time for collective action is not too late. However, it is incumbent upon those who champion voluntary alternatives to CON and other such controls to advance concrete and acceptable proposals which have the potential for achieving real health care cost containment over the long term. Too often the pleas of provider interests for voluntary restraint appear only when the threat of further regulation is imminent. Despite this skepticism, I share the hope that voluntary efforts can lead to a more constructive approach to the ills of our health care system than has existed in the recent past.

Donald C. Williams, Chief
Medical Care Standards
Rhode Island Department of Health

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RHODE ISLAND MEDICAL SOCIETY FOUNDATION

The officers and Council of the Rhode Island Medical Society established the RIMS Foundation in 1983 to promote charitable, educational, and scholarly endeavors in the service of medical care and public health.

While these have always been the basic objectives of the Society, tax laws make the new RIMS Foundation the appropriate vehicle for furthering them in the 1980s. Among the activities of the Foundation will be:

- public information programs to promote awareness of the malpractice crisis and an understanding of other problems facing America's health care system
- continuation of the long-standing work of the Benevolence Fund to help needy physicians and their families
- scholarships, grants, and loans to medical students
- support for other educational and scholarly endeavors, including continuing medical education activities and the Society's Library

Already a series of seminars to address malpractice issues is in the planning stages for this fall.

Because the Foundation is recognized as a 501.c.3. organization under the Internal Revenue Code of 1954, all contributions to the RIMS Foundation are tax-deductible. (In contrast, contributions to RIMS itself are not. Only your annual RIMS dues are tax-deductible since they represent a professional business expense.)

Below are the names of our colleagues who have contributed to the Foundation all or part of their share in the recent settlement of the *Barry* case. To date, this effort alone has raised more than \$37,000 for the Foundation.

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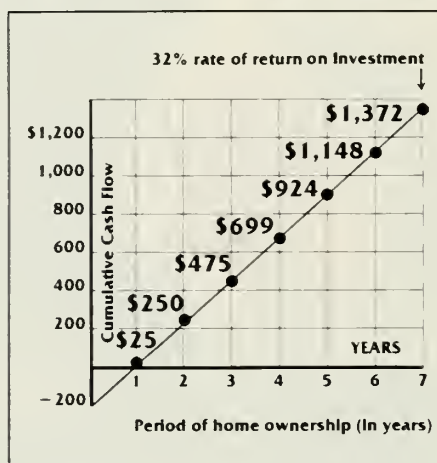
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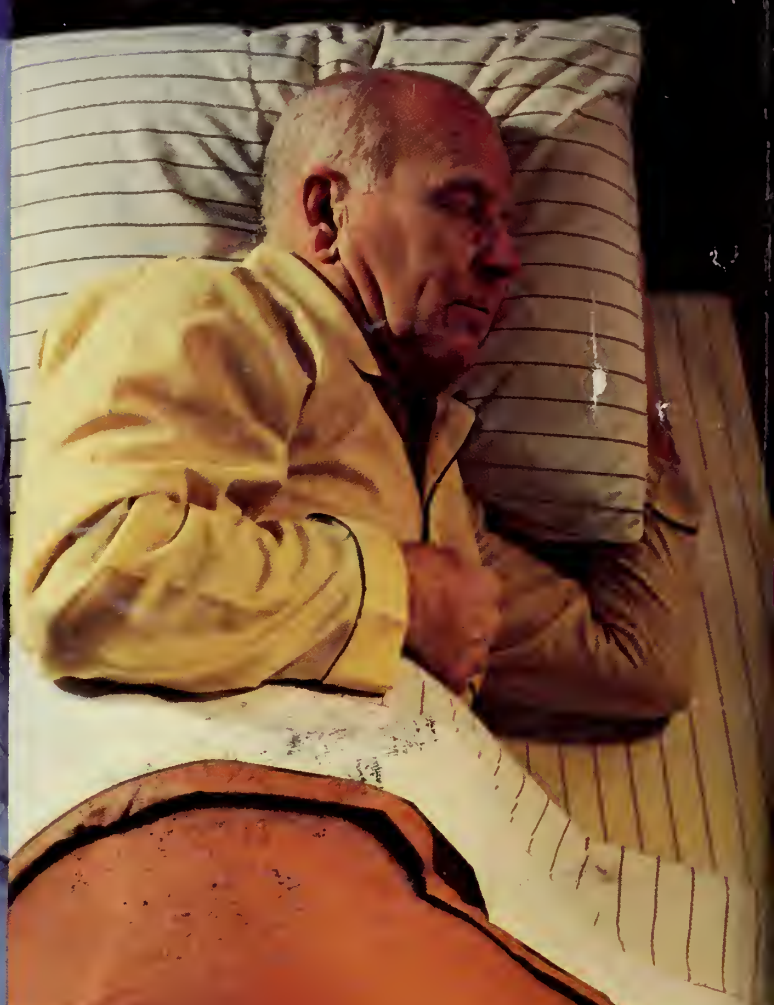
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Rhode Island Medical Journal

October 1984
Volume 67, Number 10

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See page 431

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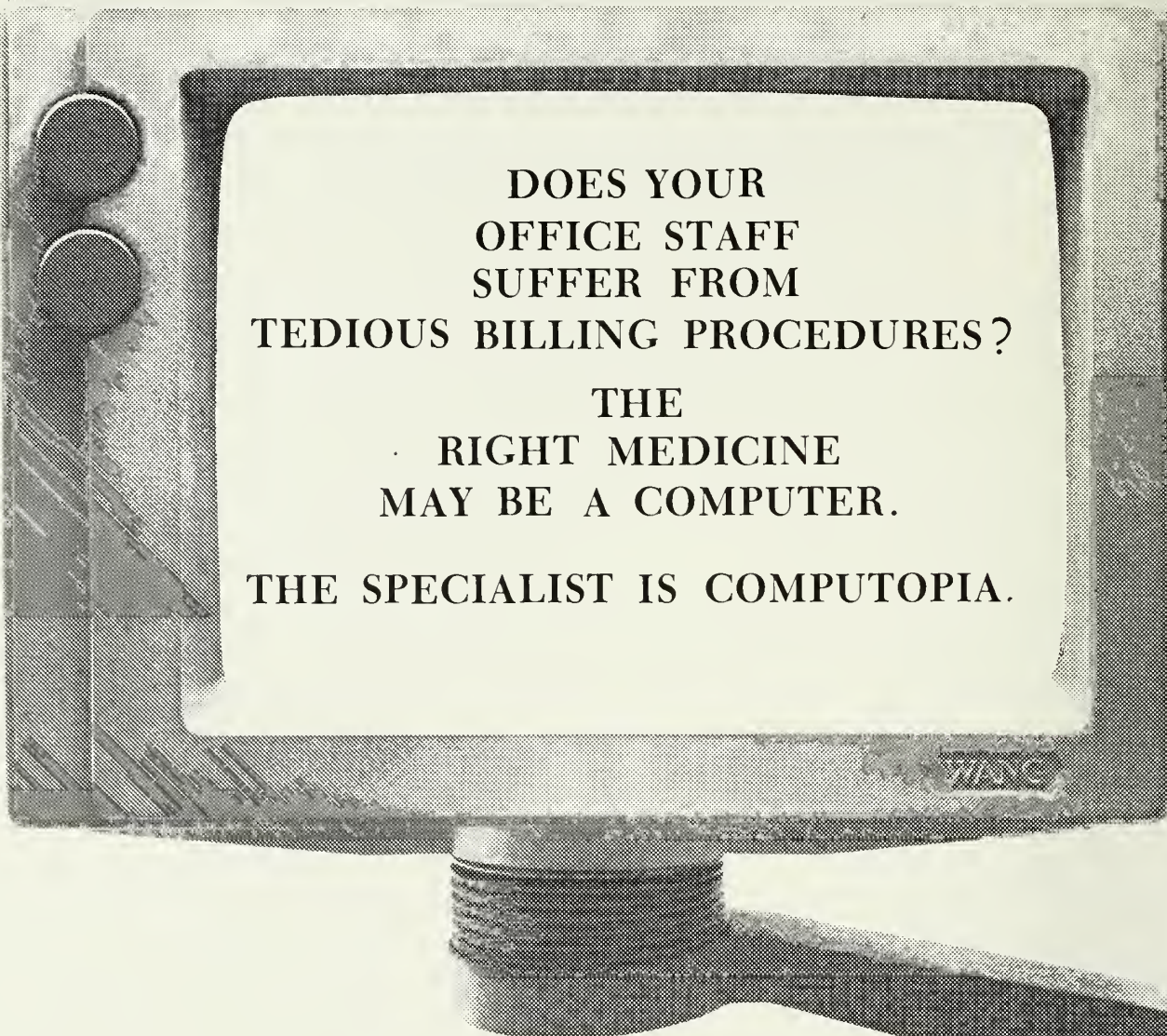
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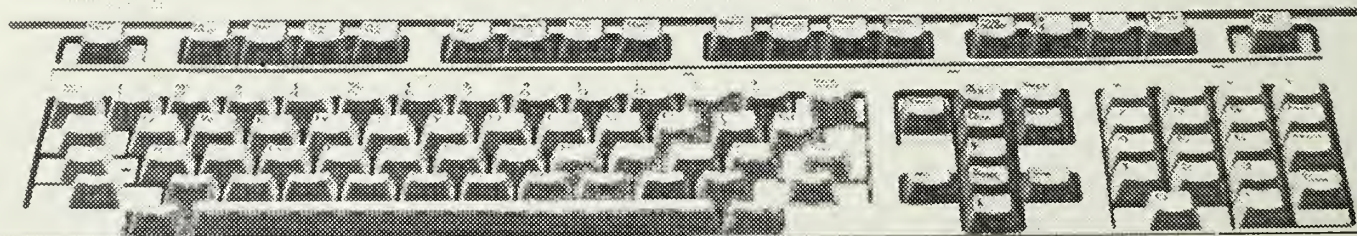
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Newsletter

RHODE ISLAND MEDICAL SOCIETY
October 1984

Paul J.M. Healey, MD, President
Wendy J. Smith, Editor

SOCIETY MEETS WITH GUBERNATORIAL CANDIDATES

The growing malpractice crisis dominated the agenda during separate breakfast meetings with the candidates for the Democratic gubernatorial slot, Mayor Joe Walsh of Warwick and state treasurer Anthony Solomon. Solomon received a decisive margin in the September 11 primary and faces Republican Edward DiPrete in the November 6 election.

The August 29 and September 5 breakfast sessions were organized to provide RIMS members and their guests with the opportunity of meeting the candidates informally. After brief opening remarks, each fielded questions from the audience on such diverse issues as the impact of the malpractice crisis on medical care, optometric drug legislation, public schools, and taxes.

Solomon also was questioned about his recently-released position statement on health which, among other things, calls for additional attention to "health promotion and disease prevention." In his written statement, the Democrat also pledged to improve health care services for the elderly, initiate health education programs for all Rhode Islanders, and appoint a blue-ribbon commission charged with "reviewing the major factors which influence health cost escalation." A pharmacist by training, Solomon also said that he would encourage the use of neighborhood health centers as a less expensive alternative to hospital emergency rooms.

A similar breakfast session is being scheduled with Mayor Edward DiPrete of Cranston in October.

While Society representatives have met frequently with elected officials in the past, the breakfast series marks the first time that meetings have been held with political candidates. RIMS President Dr Paul J.M.

CANDIDATES' BREAKFASTS (continued)

Healey said, "The success of the meetings is a clear indication that the time to talk with elected officials is before the election. I am planning to recommend that a similar series of 'breakfast with the candidate' be held during the 1986 political campaign."

RIMS REPRESENTED AT AMA COUNCIL

The Society was represented at the September 21 meeting of the American Medical Association Council on Legislation by Drs Paul J.M. Healey, President; Norman A. Baxter, Executive Director; and Newell E. Warde, Assistant Executive Director. The AMA Council, which met in Boston, is responsible for recommending positions on federal legislation and regulations to the AMA Board of Trustees.

The Medicare fee freeze and other requirements of the Deficit Reduction Act of 1984 dominated the agenda. In late August, the AMA announced plans to challenge the constitutionality of some provisions of the new law. Among other requirements, the act: 1) freezes physician reimbursement under the Medicare program at the current level from July 1, 1984 until September 30, 1985; 2) creates a new class of "participating physicians," ie, those who agree to accept assignment of Medicare benefits as payment in full for all Medicare patients; and 3) requires close federal scrutiny of all claims submitted by non-participating physicians. Commenting on the planned lawsuit, AMA Board Chairman John Coury said that " . . . the act singles out physicians, alone among all segments of our society, by forbidding them from entering into contractual arrangements with patients."

In other actions, the AMA Council also reviewed provisions of HR 5400, the Alterna-

AMA LEGISLATIVE COUNCIL MEETS (continued)

tive Medical Liability Act, and proposed model state legislation on medical review boards. Introduced by Reps W. Henson Moore (R, LA) and Richard Gephardt (D, MO), HR 5400 would apply a modified "no-fault" approach to patient care paid for by the federal government. These patients include Medicare beneficiaries, Medicaid recipients, military personnel, veterans, and federal employees. Under the proposal, physicians and hospitals would be permitted to offer a settlement within six months of the occurrence of the alleged incident. The settlement is to include payment for such "net economic losses" as out-of-pocket expenses, reasonable legal charges, the costs of medical care, lost wages, and rehabilitation expenses. Once the offer had been made, the patient would forfeit all rights to judicial review except to dispute the appropriateness of the settlement on economic grounds.

In testimony before the US House of Representatives Subcommittee on Health, the AMA expressed concern that HR 5400 would raise insurance costs because physicians and hospitals probably would settle marginal claims which would not be pursued under the present system. The bill represents the first time that a potential federal solution to the malpractice crisis has been proposed.

Other federal legislation reviewed by the AMA Council included such diverse topics as implementation of peer review organizations (PROs), the so-called "Baby Doe" legislation covering the rights of handicapped infants, organ transplantations, the administration of heroin to terminal cancer patients, and insurance coverage of preventive health services.

SOCIETY ENDORSES 911 EMERGENCY NETWORK

At its August meeting, the Council of the Rhode Island Medical Society called on RIMS members to support a \$5 million bond issue for financing a 911 emergency access telephone number throughout the state.

In an action long advocated by the Society, the General Assembly earlier this year approved installation of a 911 sys-

COUNCIL URGES SUPPORT (continued)

tem, subject to voter approval of the November 1984 referendum. Rhode Island is one of the few jurisdictions in the country without a three-digit emergency access number.

Representing RIMS and the Rhode Island Chapter of the American College of Emergency Physicians before the Senate Health, Education, and Welfare Committee, Dr Jacek B. Franaszek emphasized that a 911 system is essential to providing adequate emergency medical services. Dr Franaszek serves as Director, Department of Emergency Medicine, Rhode Island Hospital. Rhode Islanders currently are confronted with a "bewildering" array of emergency telephone numbers, he told the committee. The delays resulting from the present system are intolerable in situations where timely intervention by appropriate medical personnel is crucial.

A guest editorial by Dr Franaszek appears on page 433 of this Journal.

TECHNOLOGICAL INNOVATIONS TARGETED AS CULPRIT IN RISING MEDICAL COSTS

Technological innovations are the "primary cause of the increase" in US health care costs, according to a report published by the US Congressional Office of Technology Assessment (OTA) in late July.

Costs related to medical technology have contributed substantially to the 19 per cent increase in Medicare expenditures since 1974. The OTA report also noted that Medicare reimbursement policies have encouraged the growth of technology and made it available to more and more patients. "The inappropriate use of medical technology is common and raises Medicare and health system costs without improving the quality of care," the report alleges. OTA staff further postulate that surgical procedures, laboratory procedures, and other tests frequently are overutilized, resulting in more complex interventions and longer hospital stays.

Despite the alleged scope of the problem, however, the OTA recommends against rationing as an effective means of controlling Medicare costs and instead suggests the development of alternative health

care delivery systems as the "best approach to the problem." OTA recommendations frequently are used as the basis of Congressional deliberations on Medicare financing.

MILLARD NAMED TO AMA COMMITTEE

Dr Charles E. Millard, RIMS president from 1981-1982, has been named by the AMA Board of Trustees as one of eight members of the AMA Ad Hoc Panel on Organ Transplantations of the Council of Scientific Affairs. The new group will be charged with developing AMA policy on organ transplantations. A permanent deacon of the Providence Diocese, Dr Millard also served on the prestigious National Institutes of Health Consensus Development Conference on Liver Transplantations. The NIH group was convened in June 1983.

GELCH NAMED FOR NATIONAL AWARD

Dr Melvyn Gelch was nominated by RIMS for the 1985 Benjamin Rush Award for Citizenship and Community Service of the American Medical Association. Dr Gelch was the principal force behind a home rule charter for the City of Providence. After the city was granted home rule status by the General Assembly, he served as chairman of the commission which drafted the current charter.

Dr Gelch achieved national prominence earlier this year as a result of his successful efforts to prevent a former Providence mayor, who had been forced to resign after a felony conviction, from seeking re-election.

In his nomination letter to the AMA, RIMS President Dr Paul J.M. Healey said, "Dr Gelch embodies the sense of civic responsibility originally displayed by Benjamin Rush. Without concern for his own welfare or that of his family, he has shown unrelenting zeal in his efforts to assure good government for the citizens of Providence. Through his example, Melvyn Gelch has demonstrated that it is possible for concerned citizens to influence governmental and judicial decisions of considerable significance to the community."

Dr Gelch currently serves as RIMS Vice-President.

DIABETES ASSOCIATION ORGANIZES CAMPAIGN

As part of a national campaign to stimulate awareness of Type-II diabetes, the Rhode Island Diabetes Association is establishing a committee which will focus on the continuing educational needs of physicians, nurses, and other health professionals who treat diabetic patients. Earlier this year, the American Diabetes Association launched a \$4 million program designed to reach all primary care physicians in the US by 1986.

The Rhode Island affiliate also recently created a multi-disciplinary patient education committee consisting of professionals participating in the Diabetes Control Out-patient Education Program; patient educators at hospitals, nursing homes, and other health care facilities; and all interested health professionals.

Further information concerning both groups is available from the association at 401/331-0009.

LUNG CANCER DEATHS INCREASE

Lung cancer has replaced carcinoma of the breast as the leading cause of cancer mortality among American women between the ages of 65 and 74 years, according to a recent report from the National Center for Health Statistics. The Center attributes the growth in lung cancer deaths to the "increased smoking rate of females now entering this age group."

The RI Department of Health, however, recently reported that cardiopulmonary disease remained the primary cause of death among Rhode Islanders of all ages last year. The 1983 Provisional Report Summary, issued by the Division of Vital Statistics, does not include mortality rates by age group or sex.

Among the malignant neoplasms, which are the second leading cause of death, carcinoma of the digestive organs ranked the highest at a rate of 68.3/100,000, followed closely by lung cancer at a rate of 61.3/100,000. While the 1983 mortality rate for lung cancer showed a 1.1 per cent increase over last year, the comparable increase in deaths from all malignant neoplasms was three per cent. The report also notes a 50.3 per cent hike in the number of deaths resulting from pneumonia.

IS ADVERTISING BY PHYSICIANS ETHICAL?

We frequently receive questions at the Society's offices from physicians and the public concerning the appropriateness of advertisements by physicians. Are they ethical? What is considered within the bounds of good taste? The following information is from the 1983 *Current Opinions of the AMA Judicial Council* and a brochure, "Voluntary Guidelines for Physician Advertising," published by the Hennepin (MN) County Medical Society. Specific questions should be sent to the Mediation Committee, Rhode Island Medical Society, 106 Francis Street, Providence, Rhode Island 02903.

- *Is advertising by physicians ethical?*

It is acceptable for a physician to advertise the availability of his or her services. While advertisements may be included in any form of public communication (such as newspapers, magazines, telephone directories, radio, and television), they should be restricted to the geographic area where the physician maintains an office or where most of his or her patients live and work.

- *What information may be included in an advertisement?*

Advertisements must be factual, direct, dignified, and readily understandable. They may include the following: the physician's name; name of the medical group with which the physician is associated; names of professional associates affiliated with the same group; office address and telephone numbers; office hours; educational background; available credit or other methods of payment; willingness to accept Medicaid patients; willingness to accept Medicare assignment; whether or not a participating member of Blue Shield; and specialization or limitations of the physician's practice. Specialty or subspecialty designations must be limited to those boards recognized by the American Board of Medical Specialties in which the physician is certified.

Advertisements must *not* be misleading either through omission of significant information or false representation. Statements about the quality of medical services are difficult, if not impossible, to verify and measure against objective standards. Advertisements may not include patient testimonials about the physician's skills or unsupported claims of special expertise.

The *Current Opinions* specifically note:

"A statement that a physician has cured or successfully treated a large number of cases involving a particular serious ailment may imply a certainty of result and create unjustified and misleading expectations in prospective patients."

- *What about community programs, health fairs, and screening programs?*

Physicians have a responsibility to participate in programs -- such as giving speeches to civic or church organizations -- which result in improved community health. Well-designed health fairs and screening programs also may benefit the public's health. It is appropriate to identify physicians participating in community services by name, specialty, and medical group or hospital affiliation. Physicians in these situations, however, must avoid self-aggrandizing statements which imply that they have unique qualifications or expertise.

Rhode Island Medical Journal

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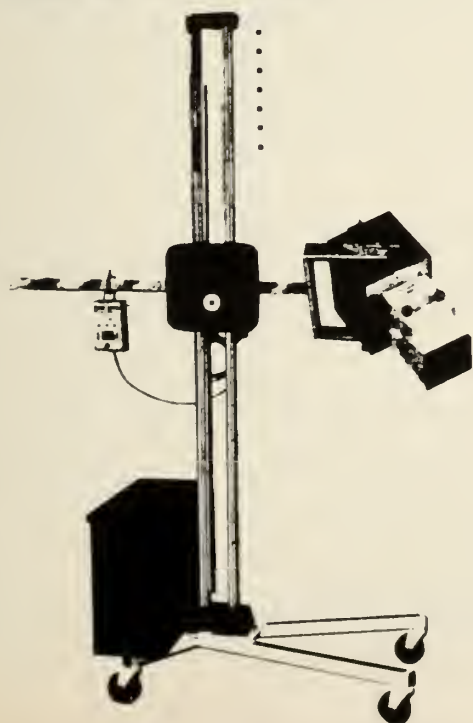
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Treatment of physicians for alcohol addiction shows a favorable outcome in 83 per cent of cases, and treatment of physicians for drug addiction has a 95 per cent success rate. More than 70 per cent of the physicians entering treatment return to the active practice of medicine.

The Rhode Island Medical Society Committee on Impaired Physicians, chaired by Dr Herbert Rakatansky, meets monthly. It is a standing committee of the Society charged with "helping physicians whose professional judgments and capabilities are impaired by their difficulties with chemical dependency or other illnesses."

The Committee handles inquiries in *complete confidence*. If you know of a physician who needs an advocate and support in obtaining necessary treatment, please call or write Dr Rakatansky c/o The Committee on Impaired Physicians, Rhode Island Medical Society, 106 Francis Street, Providence 02903 (401/331-3207).

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COVER

Detail from lateral skull film showing greatly magnified view of the pituitary resting in the sella turcica with the anterior injection of the inferior hypophyseal artery. See pages 437 and 443.

Photograph provided courtesy of Toussaint A. Leclercq, MD.

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EDITORIAL

911: A Call for Action

Jacek B. Franaszek, MD

A child sees his mother floating face down in the swimming pool. He dials 911. A shopkeeper is stabbed in the course of a robbery. He dials 911. A housewife, upon seeing her husband collapse, dials 911. In all of these commonplace but true-to-life media reports, the rescue personnel arrive promptly, and the endings are happy.

While 911 does not exist in Rhode Island, it has a chance in November when voters will be asked to approve a \$5 million bond issue to install the necessary equipment and provide operating costs for 18 months. Subsequent costs would be approximately 25 cents per citizen each month. The projected system involves a maximum of eight regional public service answering points, staffed by trained operators selectively routing calls to rescue, fire, and police in local jurisdictions. Automatic number and location identification would allow the dispatch of appropriate personnel even if the caller were unable to complete the call. It also would reduce the number of false alarms by providing a cross check of the origin of the call.

In addition to improving public safety access, the 911 system offers the following advantages: 1) an easy-to-remember, simple-to-dial number which precludes the necessity of dialing a seven-digit number which varies from community to community; 2) accessibility of the number to children; 3) reduction in response time by rescue personnel, both because of the decreased amount of time required to dial the number and because

of selective routing by a trained operator; and 4) accessibility to rescue by those who do not speak English or cannot talk, as in the case of a myocardial infarction (MI) victim.

The reduction in response time is crucial to providing an adequate response by emergency personnel. The rapidity with which a cardiac arrest victim is resuscitated affects both short- and long-term survival. If cardiopulmonary resuscitation is initiated within four minutes of an acute MI, the chances of survival are enhanced during the immediate post-arrest period. Moreover, the survival rates of such victims four years after the incident also are improved. If advanced life support is administered within eight to ten minutes, survival rates, both short- and long-term, improve markedly. The few minutes saved by an emergency telephone number have a profound bearing on outcomes in cardiac patients. Earlier intervention by trained emergency medical technicians will help assure survival of these victims.

Trauma victims also will benefit from "on-the-scene" intervention. In trauma cases, the critical variable is not extensive field intervention by paramedics, but prompt access to definitive care by physicians and nurses. It must be emphasized, however, that the immediate provision of field stabilization procedures plays a significant role in improving the morbidity and mortality of trauma patients.

The emergency patient or caller is faced with a bewildering array of some 50 emergency telephone numbers throughout the state. Implementation of a three-digit number will allow more rapid dispatch of suitably-trained help. The passage of the bond issue in November is in the best interest of our patients and ourselves. The physician community should support 911 and strive to educate other health care providers and the public as to its importance. ■

Jacek B. Franaszek, MD, is Director, Department of Emergency Medicine, Rhode Island Hospital, Providence; and Associate Professor of Surgery (Emergency Medicine), Brown University Program in Medicine. He is a fellow of the American College of Emergency Physicians.

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Big Brother — The 1985 Version

George Orwell's prophetic novel, *1984*, has proven to be a unique and detailed description of what can happen when Big Brother reduces the citizenry to blips on a chip.

It is incredible, but a fact, that the recent crisis generated by the implementation of the Deficit Reduction Act of 1984 may pale in comparison to two reports expected next year from the Office of Technology Assessment (OTA) and the Department of Health and Human Services (DHHS). Congress directed both agencies to investigate the advisability and feasibility of making payments for physicians' services to hospital inpatients on the basis of diagnosis-related groups (DRGs).

Briefly, the data base to be accumulated for these reports through the potential of computer-gathered and stored profiles will document the following information:

- (1) *Beneficiaries and utilization*: The total number of eligible Medicare patients who are hospitalized, their length of stay, and the type of services provided.
- (2) *Providers*: All services, whether a coronary by-pass, concurrent care, or a consultation, performed by physicians and non-physicians in the care of beneficiaries (ie, patients) will be recorded in detail.
- (3) *Procedures*: This will be based on the *Current Procedural Terminology* (4th Edition) (CPT-4) code manual, and will include the frequency of procedures, as well as who performed them.
- (4) *Prevailing charge file*: Information will be accumulated concerning the fees submitted



Paul J. M. Healey, MD

by all providers, whether specialist or generalist, and whether for procedural or cognitive services.

These data will be programmed into the overall cost of payment to physicians. But it does not end there. *Physicians' incomes* also will be entered into the computer analysis. While "advisory committees" representing physicians and professional organizations will be provided with an opportunity for reviewing the findings and making recommendations, this obvious tokenism will have no role in the final compilation of planned new laws, rules, and regulations. These will be drafted by staff from the Health Care Financing Administration, the Department of Health and Human Services, and the Office of Technology Assessment. They will not be beholden to anyone except the payer for Medicare benefits — Big Brother.

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Evaluation of Transsphenoidal Hypophysectomy in the Management of Metastatic Breast Carcinoma

Hormone Responsiveness and the Interval between Initial Diagnosis and Hypophysectomy Provide the Most Reliable Predictors of Success

Toussaint A. Leclercq, MD, FACS, FICS

Robert E. Knisley, MD

Richard P. D'Amico, MD

Joseph DiBenedetto, Jr., MD

Hypophysectomy, or resection of the normal pituitary gland, has been advocated as a mode of therapy for advanced breast or prostatic cancer, diabetic retinopathy, and disseminated melanoma.¹⁻⁴ The indications for hypophysectomy have narrowed with experience, however, and the procedure now is considered as appropriate only in the management of metastatic breast or prostatic carcinoma. Hypophysectomy has been utilized successfully since the early 1950s in the treatment of breast carcinoma.⁵

Despite extensive research and the accumula-

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tion of a large series of reports, the exact mechanisms of pain relief, tumor regression, or both remain unknown.⁶⁻⁷ The recent discovery of endorphins in the central nervous system and their alleviation of pain may bring new understanding of the mechanisms of pain relief. Current findings suggest the importance of two hormones, prolactin and human growth hormone (HGH), which are produced by the adenohypophysis. Their role in relieving the pain associated with metastatic breast carcinoma has been substantiated by the following findings. The administration of L-Dopa, known to reduce serum prolactin levels, has been demonstrated to alleviate pain secondary to diffuse bony metastases.⁸ Anti-prolactin serum induces regression in mammary tumors in rats.^{9, 10} Following initial relief with hypophysectomy, the injection of human growth hormone in these patients reactivates the pain mechanism.⁶ Moreover, Jules Hardy et al have reported the rapid alleviation of pain in a series of patients following transsphenoidal hypophysectomy.¹¹ This finding is confirmed by the short half-life of prolactin¹² and human growth hormone, as shown by the classic work of Hardy on hypersecreting pituitary tumors. Finally, the persistence of HGH, prolactin secretion, or both may explain those cases in which transsphenoidal hypophysectomy fails to moderate pain while a second surgical procedure resulting in total ablation is followed by complete relief.¹⁴

Indications

Since hypophysectomy is a palliative therapy for metastatic breast carcinoma, the indications must

be correlated with the risk/benefit ratio for the patient. As described by Hardy, a low incidence of mortality and morbidity is associated with the procedure.^{1, 15} Two-thirds of the patients have been shown to respond. These findings are acceptable if the benefit to the patient results in a better quality of life.¹⁶ A favorable outcome may be predicted in those patients who previously responded to hormonal therapy or other ablative procedures. Bony disease remains the primary indication. While patients with visceral involvement have a shorter survival period and a poor prognosis, they should not be eliminated as surgical candidates because of the potential pain relief and the possibility of a longer remission than would otherwise occur. It is also likely that the availability of estrogen receptor testing will refine the indications for the procedure, although a large series correlating TSH and estrogen receptor positivity is not yet available.¹⁷

The present study is based on 30 consecutive cases of transsphenoidal hypophysectomy performed at the Rhode Island Hospital, Providence, Rhode Island, in 1977 and 1978. Surgery was performed only in cases of metastatic breast carcinoma, generally after failure to respond to such treatment modalities as chemotherapy, hormonal therapy, radiation therapy, and oophorectomy.

The decision to perform the procedure was reached jointly by an oncologist and neurosurgeon. The decision to operate was based on the following criteria: the ability of the patient to tolerate surgery with reasonable risk, the predominance of bony metastases with intractable pain, good response to ovariectomy in premenopausal patients, previous response to hormonal manipulation, estrogen receptor positivity (when available), a prolonged interval between the initial diagnosis and first metastases and between the diagnosis and consideration of TSH, and lack of central nervous system involvement.

In this series of patients, the mean age at the time of the operation was 55.5 years with a mean age at diagnosis of 51.4 years. The mean interval between the initial diagnosis and TSH was 4.1 years. Among this series of patients, 13 were premenopausal and 17 postmenopausal at the time of the diagnosis.

Surgical Procedure

The sublabial midline rhinoseptal transsphenoidal approach to the pituitary gland is now standard and has been described else-

where.^{1, 11, 14, 15} Only a short description of the procedure follows below. Under general anesthesia, an incision is made in the upper gum. The nasal mucosa is elevated, and the inferior third of the nasal septum is removed. The sphenoid sinus is opened, the pituitary gland exposed through a window in the sella floor, the pituitary stalk divided, and the gland removed in one piece. Depending upon anatomical variations, a total or selective anterior hypophysectomy is performed. A watertight closure is insured by a strip of fascia, a piece of muscle, and a cartilage graft. Nasal mucosa flaps are approximated with vaseline gauze. The entire procedure lasts approximately one hour and leaves no visible facial scar.

The transsphenoidal approach to pituitary tumors has been refined by the use of radiofluoroscopic control and the surgical microscope.¹⁵ The method currently is utilized for pituitary ablation. The optic magnification and the direct illumination provided by the microscope permit excellent identification of anatomical structures, especially of the pituitary gland. With microsurgical instruments, complete ablation of the pituitary gland is assured. Panhypopituitarism is, therefore, immediate and complete.

Complications

While the procedure itself is rarely associated with morbidity or mortality, the occurrence of complications is directly related to the debilitated state of patients with advanced metastatic carcinoma. Previous therapeutic interventions delay healing and impair normal physiological defenses against infection. A careful preoperative evaluation should decrease the occurrence of complications.

One perioperative death occurred in a 59-year-old patient secondary to massive, uncontrollable bleeding. Postmortem studies revealed metastatic involvement of the sphenoid sinus and sella turcica. One patient died of respiratory failure with pleural effusion. In a 58-year-old patient who had received radiation therapy to the neck area, the postoperative course was complicated by edema of the vocal cords. Reintubation, followed by a tracheostomy, was necessary. The erosion of the subclavian artery resulted in uncontrollable bleeding and death. One patient developed postoperative meningitis secondary to a cerebrospinal fluid (CSF) leak and was successfully treated with antibiotic therapy. One patient developed a transient palsy of the sixth nerve secondary to trauma to the oculomotor nerve in the cavernous sinus. Complete recuperation occurred by the

sixth postoperative day. There were 11 transient and five permanent cases of diabetes insipidus among this series of patients. In most cases, diabetes insipidus can be controlled successfully by Atromid® (clofibrate) administered orally. Only two patients required Diapid® (lypressin) nasal spray twice daily. The replacement therapy consisted of 37.5 mg cortisone acetate and 0.1 mg Synthroid® (levothyroxin sodium) daily. As a modified surgical technique currently is available to prevent diabetes insipidus, the incidence of this bothersome complication should be decreased significantly.

Verification of Results

All procedures were performed by the same surgeon (TAL). The complete excision of the pituitary was thought to have been achieved in all cases using the technique described. Pathological verification of pituitary tissue was obtained in every case.

To shorten hospitalization and reduce costs, the postoperative endocrinological workup generally was limited to an assessment of the prolactin and human growth hormone levels. In the majority of cases, thyroid-releasing hormone prolactin stimulation was used. Excision of the entire gland was indicated by the absence of prolactin secretion above the baseline. The procedure resulted in 22 cases of confirmed total hypophysectomy and an incomplete hypophysectomy in one patient. No information was available for seven patients, including the three who died.

Discussion

The results reported following transsphenoidal hypophysectomy vary considerably from one series to another depending upon criteria used

and the hypophysectomy technique utilized. The measurement of lymph nodes, shrinking of visible tumor, radiographic calcification, and absence of new lesions may be considered as indications of an "objective remission."²⁰ It should be noted, however, that pain relief has been reported in as many as 92 percent of cases with no correlation to an "objective" remission.¹¹

While it is gratifying for the surgeon and the oncologist to substantiate the objective regression of measurable tumor deposits, the patient is more concerned with pain relief and improved daily functioning. However, an objective assessment of pain remains difficult to determine. Decreased use of pain medication is an unreliable indicator as the patient also may continue to take medication because of chronic addiction. The Eastern Cooperative Oncology Group (ECOG) evaluation method provides a useful guide to performance status (Table 1).

Pain relief: A decrease in pain medication was considered significant when a narcotic pain reliever could be replaced by a non-narcotic, over-the-counter medication, or when pain medication could be decreased by at least 75 per cent. Others were considered to be failures. Pain relief of two months or less was also considered to represent failure. Of the entire series, 19 cases were considered successful while six were failures. In two cases, the information was inconclusive (Table 2). The three postoperative deaths were eliminated from this table.

Performance status: An improvement of two points or more in the ECOG scale was considered to represent success (20 cases), while improvement of one point was considered inconclusive (one case). No change in performance status was classified as failure (seven cases, including three postoperative deaths). A change of less than two months' duration also was considered to be a failure (Table 2).

Correlation with hormonal dependency of tumor: Tumor hormonal dependency was judged on the previous response to ovariectomy or hormonal manipulation. The estrogen receptor positivity, when available, also was considered (four cases). When the criteria of decreased reliance on pain

Table 1. — ECOG Performance Status Key

0 — Normal activity
1 — Symptoms but ambulatory
2 — In bed less than 50 per cent of time
3 — In bed more than 50 per cent of time
4 — 100 per cent bedridden

Table 2. — Performance Status and Use of Pain Medication Following TSH

TUMOR TYPE	PERFORMANCE STATUS		PAIN MEDICATION	
	Response	Failure	Response	Failure
Hormonal dependent	20	4	19	2
Non-hormonal dependent	0	5	—	4
Information not available	1	—	2	—

medication and ECOG performance status are applied, it is quite evident that those patients who had responded previously to hormonal manipulation obtained more satisfactory results from transsphenoidal hypophysectomy. These results suggest that the procedure may not be indicated in patients when previous hormonal manipulations have failed.

Correlation with the interval between diagnosis and procedure: Previous studies have suggested that an increased interval between the initial diagnosis and the procedure may be a useful guide for deciding on hypophysectomy. As noted previously, the mean interval between diagnosis and TSH in the present series of patients was 4.1 years. The interval for pain responders, however, was 5.1 years. Patients who did not obtain measurable pain relief averaged 3.6 years between diagnosis and TSH. When measured against the ECOG performance criteria, the patients who responded to TSH have an average interval of 4.7 years as compared to 3.6 years for the non-responders. Both findings demonstrate that patients who responded to TSH have a diagnosis-TSH interval longer than the entire series, while non-responders have a shorter interval. A long interval, therefore, is a good indicator of a positive response to hypophysectomy.

Effects on survival: Increased survival following hypophysectomy could not be established in some series,¹⁴ while in others there appeared to be a longer survival period.² In the present series, patients responding to TSH had a significantly longer survival when compared to non-responders. In the group of responders, the survival varied between two and 46 months with an average of 19.6 months while in the non-responder group survival varied between three and five months with an average of 3.6 months.

Conclusion

The literature on hypophysectomy in metastatic breast carcinoma is reviewed, and a clinical experience with 30 cases is reported. The most favorable candidates have a history of previous response to hormonal manipulation. A long diagnosis-TSH interval is predictive of good response both in pain and performance status. Patients who responded to previous hormonal manipulation also demonstrated longer average survival. The relief of pain and a significant im-

provement in performance status was found in two-thirds of the patients. This ratio is higher when case selection is made on the basis of hormone responsiveness and the interval between diagnosis and TSH.

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Pituitary Hyperthyroidism: Report of Three Cases

This Unusual Clustering of Cases Probably Represents a Heightened Awareness and the Availability of TSH Assay

Christopher Ehmann, MD
Dennis S. Krauss, MD
Charles B. Kahn, MD

Hyperthyroidism is a relatively common disorder usually caused by diffuse goiter (Graves' disease or non-Graves' disease), multinodular goiters or toxic adenomas. The hyperthyroid state is the clinical expression of increased amounts of circulating thyroid hormones produced by a gland unresponsive to normal control mechanisms. It is usually treated by blocking thyroid hormone synthesis, by medical or surgical ablation of the thyroid gland, or by treatment of symptoms.

Normally, thyroid secretion of thyroxine (T_4) and triiodothyronine (T_3) is modulated by the thyroid-stimulating hormone (TSH) produced in the anterior pituitary and released into the systemic circulation. The secretion of TSH is, in turn, controlled by the thyrotropin-releasing hormone (TRH) secreted from the hypothalamus. Increased amounts of circulating thyroid hormones inhibit the production of TSH in the anterior pituitary. It is presently unclear which

factors regulate hypothalamic TRH secretion.¹ Thus, several points exist at which insensitivity to a controlling hormone or overproduction of such a hormone could produce hyperthyroidism. In the usual case of hyperthyroidism, an elevated circulating level of T_4 or T_3 suppresses TSH secretion in low levels. The presence of a normal or elevated TSH level in a patient with an elevated T_4 suggests the diagnosis of inappropriate TSH secretion.

Gershengorn has classified the potential abnormalities that might lead to inappropriate TSH secretion: pituitary tumors which produce TSH, target organ resistance to thyroid hormones, ectopic TSH production, abnormal stimulation of TSH production by TRH or other substances, and defective suppression of TSH secretion.² There have been 33 cases of TSH secreting adenomas³ reported to date and several cases of pituitary resistance to the normal effects of thyroid hormones.² While there are numerous reports of ectopic production of a substance with TSH activity, particularly in hydatidiform moles, this substance differs from pituitary TSH.⁴ Cases of true ectopic TSH secretion await discovery. Examples of abnormal stimulation of TSH or TRH by other substances, or defects in the normal suppression of TSH also have not been reported as yet.

Described are three patients recently seen with TSH-secreting pituitary adenomas. Many more patients with inappropriate TSH secretion probably will be discovered because of the wider availability of accurate assays. It is important to detect cases of inappropriate TSH secretion because the majority of these patients have pituitary adenomas which can lead to such neurologic se-

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quelaes as visual field defects, headache, increased intracranial pressure, or even death. Treatment of pituitary adenomas clearly has been shown to benefit these patients, both by relieving their symptoms of hyperthyroidism and by preventing further neurological deficits. The diagnostic procedures, treatment options, and prognosis of these patients are reviewed below.

Case Reports

Case Report 1: A 57-year-old black female initially presented in August 1979 with bitemporal hemianopsia. There was a history of hypertension and diabetes. In 1956 she had undergone a partial thyroidectomy for a cold nodule, and in 1968 was treated with radioactive iodine (^{131}I) for symptomatic hyperthyroidism. She displayed no clinical signs until 1979 when visual field defects were noted. A computed tomographic scan showed a suprasellar mass which was confirmed by angiography. Endocrine studies at that time showed T_4 of $8.0\mu\text{g/dL}$, TSH of $92.7\mu\text{U/mL}$ (normal $0-9.5\mu\text{U/mL}$), luteinizing hormone of $106\mu\text{U/mL}$, and prolactin of 312 Iu/mL . Human growth hormone was less than 1.1 ng/mL , and morning cortisol was $17.2\mu\text{g/dL}$. Except for the TSH level, all were within normal limits. Although a T_3 uptake was not obtained at this time, the values were normal at all other times tested.

The tumor was then debulked, but could not be completely excised. On examination of frozen section, the tumor appeared to be a chromophobe adenoma. Postoperative external radiotherapy (4500 rads) was performed but was unsuccessful in improving the visual fields. The patient was discharged on prednisone, and she remained clinically euthyroid.

During the next year, the hemianopsia progressed. A CT scan showed recurrent tumor, and she underwent a transsphenoidal hypophysectomy. A chromophobe adenoma was again revealed on histological examination, and immunologic staining showed a predominance of TSH-secreting cells. The visual fields did not improve. Since a metyrapone test was abnormal, the patient was continued on prednisone. A TRH stimulation test was performed, and the TSH rose from a baseline of $36.5\mu\text{U/mL}$ to $71.0\mu\text{U/mL}$ one hour after intravenous injection of 500 g of TRH. The prolactin level measured during that same test rose normally from 32.5 ng/mL to 59.0 ng/mL thirty minutes after TRH. An L-Dopa stimulation test for human growth hormone showed a subnormal rise from 1.2 to 1.7

ng/mL at thirty minutes. A rapid Cortrosyn[®] stimulation test was normal with serum cortisol rising from 8.6 to $22.5\mu\text{g/dL}$ after 25 units of Cortrosyn[®].

Over the next six months the patient did well. Her T_4 and T_3 uptake remained normal and TSH was $69.2\mu\text{U/mL}$. Six months later the TSH was noted to rise even further, and a CT scan showed an increase in the size of the mass. At that time, thyroid function tests showed T_4 of $6.8\mu\text{g/dL}$, T_3 uptake of 27.8 per cent, T_3 by radioimmunoassay of 104 ng/dL (normal 100 to 190 ng/dL), and a TSH greater than $50\mu\text{U/mL}$. Several months later the patient reported a progressive narrowing in her visual fields which was confirmed by formal testing. After bromocriptine therapy was initiated, the TSH level initially decreased from $72\mu\text{U/mL}$ to $23.9\mu\text{U/mL}$ and then rose again despite continued treatment. A regimen of L-thyroxine was started. Although the TSH fell to less than $50\mu\text{U/mL}$, it again increased despite continued treatment. Other thyroid functions remained normal. A series of neurological events followed, leaving the patient bedridden and aphasic. The CT scan remained unchanged. She was discharged on L-thyroxine, and now resides in a nursing facility.

Case Report 2: A 27-year-old white male underwent a subtotal thyroidectomy in 1975 for hyperthyroidism thought to be secondary to Graves' disease. He developed symptomatic hypothyroidism, and L-thyroxine was initiated. On 0.15 mg of L-thyroxine, the T_4 was 9.3 ng/dL and TSH was $33\mu\text{U/mL}$. Because of these values, the dosage of L-thyroxine was increased to 0.2 mg daily, and thyroid studies showed the T_3 uptake of 53 per cent (normal 35 to 45 per cent), T_4 of 14.5 ng/dL (normal 5.5 to 11.5 ng/dL), and TSH of $8.7\mu\text{U/mL}$ (normal 0 to $9\mu\text{U/mL}$). He was concurrently under treatment for a seizure disorder, which had begun during childhood, with phenytoin sodium.

The patient then developed ulcerative colitis, and a six-month course of steroids was initiated. Since additional thyroid studies then revealed an elevated T_4 , L-thyroxine was reduced and discontinued. Six months after stopping thyroid replacement, the T_3 uptake was 44 per cent, T_4 12.8 ng/dL , total T_3 215 ng/dL , and TSH was $38.6\mu\text{U/mL}$. The patient was referred for an evaluation of endocrine functions in January 1982.

When first seen, the patient was asymptomatic. There were no significant findings upon physical examination, except for a thyroidectomy scar without palpable thyroid tissue. Initial studies

showed a serum prolactin level of 13 ng/mL (normal 5 to 15 ng/mL), total T_3 of 176 ng/dL, free T_4 of 1.8 ng/mL (normal 0.68 to 1.8 ng/dL), and TSH greater than 40 μ U/mL. The diagnosis of a TSH-secreting pituitary adenoma was considered, and sella tomography revealed a pituitary mass. This was confirmed by a CT scan of the sella which demonstrated erosion under the anterior clinoid. A TRH-stimulation test failed to show any increase in TSH. Additional studies showed normal levels of testosterone, human growth hormone, luteinizing hormone, and follicle-stimulating hormone. The patient refused to undergo a recommended transsphenoidal hypophysectomy.

One year later, after having sought nutrition therapy, he returned for reevaluation and underwent surgery with apparent removal of the entire tumor. Electron microscopy confirmed the gross pathological diagnosis of a pituitary tumor. The tissue was sparsely granulated and revealed a positive immunoperoxidase stain for TSH, human growth hormone, and prolactin. On postoperative testing, his gonadal and adrenal axes were normal, although the human growth hormone and prolactin could not be stimulated by hypoglycemia or by an injection of thyroid-releasing hormone (TRH). TRH also led to an abnormal, flat response of TSH from 2.9 to a peak of 4.0 μ U/mL. He is currently on thyroid hormone therapy.

Case Report 3: The third patient was 14 years old when a goiter and symptomatic hyperthyroidism were noted. She underwent a subtotal thyroidectomy, and examination of the tissue revealed diffuse hyperplasia. One year later she displayed symptoms of hypothyroidism, and L-thyroxine was prescribed. The patient was also taking haloperidol, amitriptyline, and benztropine mesylate for schizophrenia. Although she denied the presence of galactorrhea, milk could be expressed from both breasts. A CT scan revealed a pituitary tumor in the left inferior region of the sella with no destruction of the floor.

The pituitary function was evaluated after all medication was discontinued. Morning cortisols were 7.9 and 13.2 μ g/dL (normal 7.0 to 25.0 μ g/dL). After 500 g of intravenous TRH, the level of TSH remained abnormally high. On diluted specimens, the TSH rose from a baseline of 322 μ U/mL to 746 μ U/mL. The TSH alpha subunits were assayed on these specimens and rose from a baseline of 11.1 ng/mL to 19.5 ng/mL (normal less than 2.0 ng/mL) (Assays courtesy of Doctor B. Weintraub, National Institutes of Health). During this test, prolactin levels changed

little from a baseline of 110 ng/mL (normal 6.0 to 27.0 ng/mL). An insulin tolerance test was then performed, inducing a marginal fall in blood glucose from 94 to 64 mg per cent. Human growth hormone measured before and after this hypoglycemia remained unchanged, thereby displaying an abnormal response.

The adrenal corticotrophic hormone (ACTH) decreased from a baseline of 321 pg/mL to 204 pg/mL with a corresponding fall in cortisol from a baseline of 28.0 to 14.2 μ g/dL after two hours. Dexamethasone was then administered to see if TSH and alpha subunits of TSH could be suppressed. After administration of 2 mg every six hours for two days, TSH levels were drawn. The assays (courtesy of Doctor Weintraub) revealed a decrease in total TSH from 213 to 133 μ U/mL and in the alpha subunits from 7.8 to 5.4 ng/mL.

Because administration of L-thyroxine appeared to suppress TSH production, the patient was discharged on 0.2 mg/day. The most recent assay of the TSH level showed 5.6 μ U/dL. The T_4 was 16.5 μ g/dL, and the T_3 uptake was 6.4 per cent. She remains asymptomatic. To reassess the size of the tumor, CT scans will be scheduled periodically.

Discussion

These three cases demonstrate some of the characteristic features of patients with TSH-secreting pituitary adenomas. All three patients had elevated TSH levels in spite of laboratory evidence of hyperthyroidism. All had clearly demonstrated pituitary masses. Of our three patients, two have undergone resection. The tissue obtained in these cases consisted of thyrotropic cells with high concentrations of TSH.

Smallridge and Smith recently reviewed the thirty-three reported cases of hyperthyroidism attributed to TSH-secreting tumors.³ Males were affected as often as females. The ages of patients ranged from 17 to 58 years with a mean of 37 years. Most of the reported cases displayed a goiter and symptoms of hyperthyroidism. All of our patients had already undergone a thyroid resection. Only one of our patients had visual field defects, an inconsistent finding in reported cases. Clearly demonstrable masses were apparent on CT scanning.

After a TSH-secreting adenoma has been diagnosed, two additional courses must be pursued. One is functional TSH testing to delineate the influences on TSH secretion, both positive and negative, in an effort to define therapeutic

options. A detailed functional study of the other pituitary hormones also is necessary to determine the functional integrity of the remainder of the gland and to detect any other secretory deficiencies or excesses secondary to the pituitary mass.

TSH is a glycoprotein composed of two subunits, alpha and beta. Within the same species, all the alpha chains of TSH, luteinizing hormone, follicle-stimulating hormone, and human growth hormone are identical. The beta subunits differ within a species and confer both immunologic and biologic specificity. Normally, alpha subunits are synthesized in excess and beta subunit production is the rate limiting step in production of complete hormone complexes. In patients with TSH-secreting adenomas, however, the alpha subunit is increased in comparison to total TSH, as demonstrated in one of our patients.

All of our patients were stimulated with exogenous TRH. Of the two patients, two demonstrated an appreciable rise in the TSH level. As indicated by Smallridge, patients with TSH-secreting adenomas normally do not respond in such a fashion.³

Other pituitary functions were carefully tested in these patients. Baseline functions revealed normal values, except for one patient with an elevated prolactin level. Of the 33 patients reported to date, six revealed elevated prolactin and TSH levels, while six others had elevated TSH and growth hormone levels.

The treatment of TSH-secreting pituitary adenomas is pituitary ablation by surgery, radiation, or both. Most patients thus far described have become euthyroid, and TSH levels have returned to normal. Others became hypothyroid, while some have remained hyperthyroid with elevated TSH levels. For such patients several medical therapies have been initiated with varying success. Most of these trials have changed the amount of TSH secreted by a residual tumor. It remains to be seen whether this correlates with a halt to the expansion of such an adenoma. Smith noted a slight fall in TSH and alpha subunits when a course of 60 mg of prednisone was administered daily for five days. Similar results have been reported by Kourides and Lamberg with other glucocorticoids.⁵⁻⁷ One of our patients demonstrated such a suppression with dexamethasone. Dopamine was initiated by Smith without demonstrable effect.⁶ While somatostatin was shown to decrease significantly TSH secretion in two patients,^{7, 8} other authors have reported no such effect.^{9, 10} Kourides adminis-

tered T_3 to one patient with no results. Mornex was able to suppress TSH-secretion using triiodothyronine in a patient who also displayed an atypical rise in TSH when given TRH, similar to the response of two of our patients.¹¹ Both of these patients also received thyroxine which suppressed the secretion of TSH, at least temporarily. L-Dopa was shown in one patient to suppress TSH secretion.¹² Horn was able to demonstrate significant suppression of TSH and prolactin levels through a trial of bromocriptine in a patient with an adenoma which secreted both hormones.¹² In patients with prolactin-secreting adenomas, bromocriptine has been shown both to suppress secretion and to decrease the size of the adenoma as confirmed by CT scanning.¹³ In one patient with inappropriate TSH secretion but no adenoma, bromocriptine has been reported to reduce TSH levels.¹⁴ One of our patients was given a trial of bromocriptine, with only transient effect.

The first patient reported was also uncharacteristic because of her continued clinical deterioration with progressive neurological deficits. Although the length of follow-up has been relatively short, most patients with TSH-secreting adenomas have a good prognosis. The longest follow-up reported was a patient who revealed no evidence of recurrent tumor five years after a transsphenoidal hypophysectomy.¹⁵ Since most of the cases of TSH-secreting adenomas have been reported during the past ten years, it will be necessary to perform further assessments.

A TSH assay should not be performed routinely in cases of hyperthyroidism, since inappropriate TSH is a rare cause of the dysfunction. Such an assay should only be obtained in patients with hyperthyroidism resistant to therapy, or in those whose history or physical examination suggests an expanding intracranial mass. Inability to suppress TSH secretion with exogenous L-thyroxine in the hyperthyroid patient will also suggest the diagnosis.

With only 33 cases of TSH-secreting pituitary adenomas reported to date, it seems remarkable that we have treated three patients recently. It is likely that these patients represent the result of heightened awareness of the disease and the wider availability of the TSH assay. We expect a further increase in the number of cases reported. Physicians should be aware of this entity and its diagnostic and therapeutic implications.

Acknowledgments

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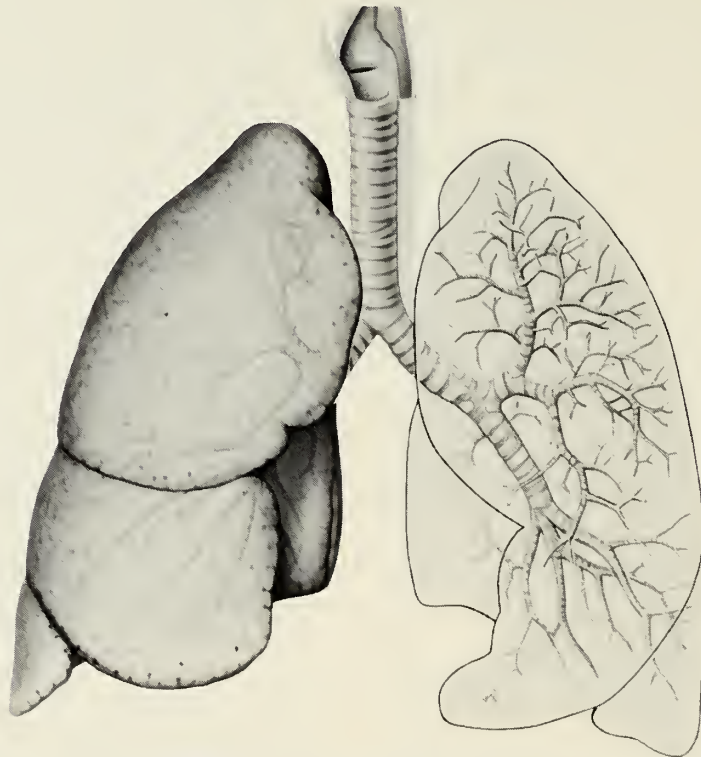
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Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae* (*Diplococcus pneumoniae*), *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci).

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Cecilor.

Contraindication Cecilor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings IN PENICILLIN SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Cecilor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins), therefore it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life threatening.

Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, manage-

ment should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions **General Precautions** — If an allergic reaction to Cecilor[®] (cefactor, Lilly) occurs, the drug should be discontinued and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Cecilor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross matching procedures, when anti-globulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Cecilor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Cecilor, a false positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest[®] tablets but not with Tes-Tape[®] (Glucose Enzymatic Test Strip, USP, Lilly).

Broad spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — **Pregnancy Category B** — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum

human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Cecilor[®] (cefactor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Cecilor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Cecilor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions Adverse effects considered related to therapy with Cecilor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100), pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Cecilor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported.

Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have

occurred in patients with a history of penicillin allergy. Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

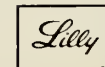
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RADIOGRAPHIC CASE OF THE MONTH

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Fig 1

History

An 86-year-old man presented to the emergency room with a complaint of the sudden onset of abdominal pain. The physical examination showed a distended abdomen, absent bowel sounds, blood in the rectum, and a temperature of 39° C. Supine (Fig 1) and left lateral decubitus (Fig 2) films were obtained.



Fig 2

For discussion turn to next page.

Radiographic Findings

The supine view of the abdomen (Fig 1) shows distended loops of the small and large bowel. In the left lower quadrant, a distended loop of the sigmoid is evident. On both sides of this loop, a dark streak can be identified which conforms to the wall of the bowel. On the decubitus view, fluid levels are demonstrated. Moreover, there are dark streaks across the right upper quadrant which conform to the margins of the liver. These dark streaks are created by a very low-density material. A comparison to the density of air in the bowel shows these streaks to be due to gas.

Diagnosis

Mesenteric infarction.

Discussion

Gas in the liver may be apparent in a localized abscess, in the gall bladder, in the biliary tree, or in the portal system. If found in an abscess or in the gall bladder, the gas should be more localized to a specific area and should be more rounded in character rather than linear and diffuse as in this case.

Linear low density streaks indicate distribution of gas in a ductal system, such as the biliary tree, or in the portal system. Because the flow of the biliary tree is from peripheral to central, gas in this system will be pushed to the hilus and appear in a central position in the liver. Since the flow of the portal tree is from central to peripheral, gas appearing in this system will be pushed to the periphery of the liver as seen in figure 2. It may

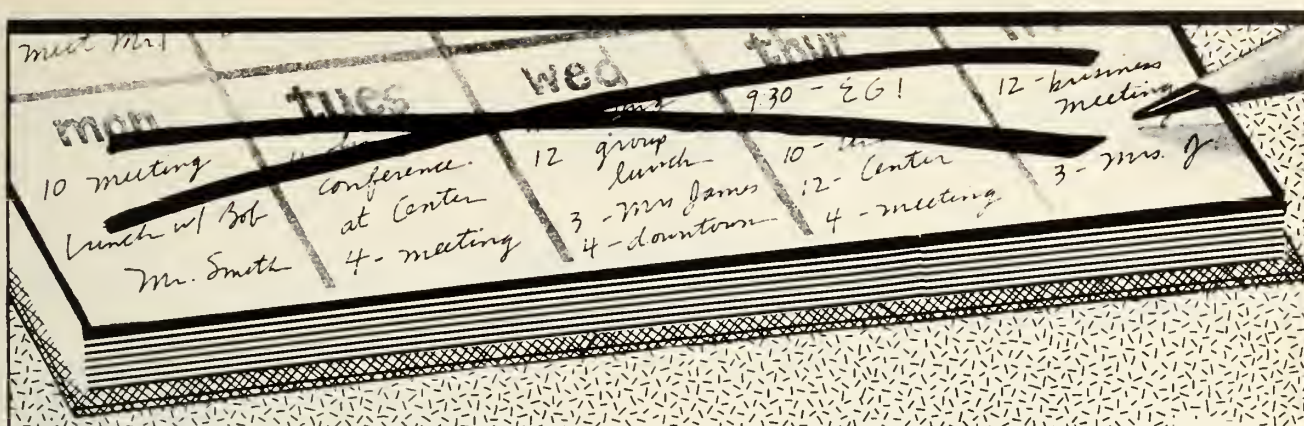
be concluded that these gas densities are in the portal system.

Gas appears in the wall of the bowel in two configurations. When seen in rounded cyst-like collections, the gas is due to pneumatosis cystoides intestinalis, a benign condition usually caused by respiratory disease which may be associated with pneumoperitoneum from rupture of the cysts. However, the identification of gas in the bowel wall in linear streaks, as in figure 1, is a grave sign. It indicates a breakdown in the mucosa of the bowel with infection of the wall by gas-producing organisms. This condition is associated with necrotizing enterocolitis or with mesenteric infarction. In both of these entities, the gas is transported to the liver through the portal venous system. When this complex of radiographic signs is seen, survival is unlikely.

From these radiographic findings, the diagnosis could be either necrotizing enterocolitis or mesenteric infarction. Necrotizing enterocolitis is seen in infancy or adulthood. When seen in an adult, it usually is caused by antibiotic therapy and the patient presents with diarrhea. There is no history of antibiotics or diarrhea in this case. The age of the patient suggests the more probable diagnosis of mesenteric infarction, secondary to atherosclerosis or embolic disease.

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Traffic Fatalities in Rhode Island: Part III

The Role of the Motorcycle

More Data Are Needed to Evaluate the Impact of Alcohol and Helmets

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Although two-wheeled motorcycles were designed and in use more than a decade before automobiles, until recently the motorcycle has not been a frequently used means of power-propelled transportation. Before 1960, motorcycles represented less than 0.5 per cent of all motor-vehicle registrations in the United States. During the past two decades, however, motorcycle usage has increased at a rate substantially greater than that for conventional motor vehicles¹ and motorcycles now account for 3.5 per cent of all registered vehicles in the nation (Table 1).

When traffic fatalities are weighted in terms of deaths per 1,000 registered vehicles per year, the mortality rates attributed to motorcycles have consistently exceeded those recorded for four-wheeled motor vehicles.^{2, 3} While motorcycles

currently represent approximately 3.5 per cent of all vehicle registrations, they account for about 10 per cent of all traffic deaths in the nation, representing a greater than three-fold relative risk when compared with four-wheeled vehicles (Table 1). In Rhode Island, during the 1977-1982 interval, 12.7 per cent of all persons killed in traffic accidents were motorcycle drivers, while an additional 1.6 per cent were motorcycle passengers.

Source of Data and Methods

As with the earlier papers concerning traffic fatalities in Rhode Island,^{4, 5} the information presented in this analysis is derived from the records of the Office of the Medical Examiner, State of Rhode Island. During the 1977-1982 interval, 97 motorcycle drivers and 12 motorcycle passengers were killed on Rhode Island roads and highways in the course of 108 separate accidents.

The following information was extracted for each of these 109 deaths: sex, age, status of victim (motorcycle driver or passenger); time of accident (month, day, hour); weather conditions at time of accident; marital and occupational status of victim; nature of accident (collision with another moving vehicle, collision with a fixed object, or overturn without prior collision); recorded use of safety helmet at time of accident; and laboratory evidence of alcohol, psychoactive drug usage, or both.

Results

The yearly distribution of the 109 motorcycle fatalities is summarized in Table 2. Total traffic fatalities involving both motorcycles and motor

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The papers in this series represent undergraduate honors studies undertaken at Brown University, Providence, Rhode Island, by Kemi Nakabayashi, Sarah C. Aronson, and Michael Siegel. At the present time, Kemi Nakabayashi is a medical student at Case-Western Reserve University; Sarah C. Aronson is a medical student at Dartmouth Medical School; and Michael Siegel continues his undergraduate studies at Brown University. William Q. Sturner, MD, is Chief Medical Examiner, State of Rhode Island, and Professor of Pathology, Brown University Program in Medicine. Stanley M. Aronson, MD, is University Professor of Medical Science, Brown University.

vehicles during the period under consideration diminished from 138 deaths in 1977 to 113 in 1982. The annual number of motorcycle fatalities, however, remained at about 18 deaths until 1982, when the incidence rose to 23, representing 20 per cent of all traffic fatalities in the state that year.* Within the comparable five-year interval, 22,401 motorcycle drivers and passengers were killed in the United States (Table 2). A slight increase in the fraction of traffic fatalities caused by motorcycle accidents is also apparent in the national data,¹ thus paralleling the observations in Rhode Island.

Ninety-six of the 97 fatally injured motorcycle drivers were male. All were white, except for one black male driver. Of the motorcycle passengers killed, 7 were female and 5 male. Only 6 of these 97 motorcycle drivers were 35 years of age or older (Table 3), and their average age was 22.4 years. All of the fatally injured motorcycle passengers were younger than 34 years with an average age of 20.2 years. Moreover, these motorcycle driver fatalities accounted for about 32 per cent of all motor vehicle and motorcycle driver deaths below the age of 24 years. In contrast, motorcycle

accidents were responsible for a very small fraction (2.8 per cent) of traffic fatalities involving drivers older than 35 years of age.

Table 4 relates the Rhode Island motorcycle driver fatalities to the month of accident. Most of these accidents occur during the summer. Indeed, during this six-year study interval, no fatal motorcycle accidents were recorded during December, January, or February. Table 4 also summarizes the national pattern of motorcycle fatalities for the year 1981.³ While some deaths are listed for the winter months, the national data also demonstrate a significant increase in motorcycle fatalities during the summer months.

The nature of the fatal impact is also analyzed in Table 4. It should be noted that 44.3 per cent of Rhode Island motorcycle fatalities are caused by a collision with another moving vehicle (in comparison to a national rate of 56.9 per cent); 43.3 per cent by a collision with a fixed object such as a tree, guardrail, or wall (national rate = 29.0 per cent) and 7.2 per cent by overturning of the motorcycle without preceding collision (national rate = 11.6 per cent). In 5.2 per cent of these fatalities, the dynamics of the fatal impact were

Table 1. — Motor Vehicle and Motorcycle Fatalities in the US (1960-1980)

	1960	1965	1970	1975	1980
Registrations (× 1,000,000):					
All vehicles	74.47	91.78	111.22	137.86	164.82
Motorcycles	0.57	1.38	2.82	4.96	5.82
Percent of motorcycles	0.8	1.5	2.5	3.6	3.5
Traffic deaths (× 1,000)					
All	36.4	47.1	52.6	44.5	51.1
Motorcyclists	0.8	1.7	2.3	3.2	5.1
Percentage of motorcyclists	2.2	3.6	4.4	7.2	10.0
Traffic deaths per 10,000 registered vehicles:					
Four-wheeled vehicles	0.38	0.41	0.37	0.25	0.23
Motorcycles	1.40	1.23	0.82	0.65	0.88
Relative risk	3.7	3.0	2.2	2.6	3.8

Table 2. — Motorcycle Fatalities in Rhode Island (1977-1982): Victim Status and Year

Victim Status	1977	1978	1979	1980	1981	1982	Total
Rhode Island:							
Motorcycle driver	17	15	12	16	17	20	97
Motorcycle passenger	1	3	2	2	1	3	12
Total motorcycle fatalities*	18	18	14	18	18	23	109
Total traffic fatalities	138	125	136	131	123	113	766
Percentage of motorcycle fatalities	13.0%	14.4%	10.3%	13.7%	14.6%	20.4%	14.2%
United States:							
Total motorcycle fatalities*	3,938	4,359	4,583	4,879	4,642	NA	22,401†
Total traffic fatalities	47,878	50,331	51,093	51,091	49,268	NA	249,661†
Percentage of motorcycle fatalities	8.2%	8.7%	9.0%	9.5%	9.4%	NA	9.0%

* Driver and passenger.

† Totals for 1977-1981 only.

Table 3. — Motorcycle Fatalities in Rhode Island (1977-1982): Victim Status and Age

	Age (in years)					Total
	0-14	15-24	25-34	35-44	45+	
Victim Status (Rhode Island):						
Motor cycle driver, male	2	56	32	3	3	96
Motorcycle passenger, male	0	4	1	0	0	5
Motorcycle driver, female	0	0	0	1	0	1
Motorcycle passenger, female	0	6	1	0	0	7
Total motorcycle fatalities	2	66	34	4	3	109
Total traffic fatalities	61	296	157	59	193	766
Percentage of motorcycle fatalities	3.3%	22.3%	21.7%	6.8%	1.6%	14.2%
Motorcycle driver fatalities						
(percentage by age) (1977-1982):						
Rhode Island	2.1%	57.7%	33.0%	4.1%	3.1%	100%
US	2.6%	52.1%	30.8%	8.7%	5.8%	100%

not apparent to the investigators (national rate = 2.4 per cent). In Rhode Island, the fatal motorcycle accidents occurring in the summer months are more commonly associated with fixed object impact, while spring and autumn motorcycle driver deaths result more frequently from collision with another moving vehicle.

Table 5 analyzes these 97 motorcycle driver fatalities in terms of the day of the week. More accidents are recorded on Saturdays and Sundays than on midweek days. Furthermore, a greater percentage of the fatal weekend accidents takes place at night than is the case with the weekday accidents. The frequency of detectable alcohol is also higher in the weekend motorcycle driver fatalities. Of the weekend fatalities listed in Table 5, 63 per cent show detectable blood alcohol concentrations, and over one-third yield concentrations higher than 0.16 per cent. In contrast, fewer than one-third of the midweek fatalities are associated with any detectable blood alcohol.

Motorcycle driver fatalities in terms of hour of day, nature of impact and blood alcohol concentrations are summarized further in Table 6. About 60 per cent of these fatal accidents occur between the hours of 6 pm and 6 am. Most motorcycle accidents during the daylight hours are customarily the result of collision with another moving vehicle. After sundown, collision

with fixed objects such as highway guardrails are more commonly the basis of the fatal event.

The extent to which detectable blood alcohol is associated with motorcycle fatalities varies widely according to the hour of the accident. None of the ten motorcycle drivers who were killed between 6 am and noon had any detectable blood alcohol. In the accidents between noon and 6 pm, 25 per cent of the victims showed detectable blood alcohol concentrations. Of the accidents occurring between 6 pm and midnight, this frequency rose to 58.1 per cent, and, in accidents between midnight and 6 am, 70 per cent of the fatally injured motorcycle drivers had detectable blood alcohol levels.

Table 7 summarizes information concerning whether a protective helmet was worn by the motorcycle driver at the time of the fatal accident. In the 57 motorcycle driver fatalities where information concerning helmet use was available, there does not appear to be any significant correlation between driver age and the wearing of a protective helmet. Although there was an overall 25.6 per cent helmet-usage among the 97 fatally injured drivers, this rate is not randomly distributed. During the daylight hours, more than 50 per cent of fatally injured motorcycle drivers were shown to be wearing protective helmets at the time of fatal impact. From 6 pm until midnight, this rate diminished to 29.6 per cent and between midnight and 6 am, only 23.1 per cent of these fatally injured drivers were wearing helmets.

Police records indicate that seven of the 97 motorcycle driver fatalities were the result of vehicle overturn prior to collision. Information concerning these accidents is analyzed further in Table 8. All of the drivers were white males with an average age of 26.4 years. Except for one

* The formal inquiry pursued by this series of papers is confined to the years 1977-1982. Because of the increasing role of the motorcycle in Rhode Island traffic fatalities, however, the authors also investigated the recently collected data for 1983. There were 22 motorcycle fatalities (17 drivers, five passengers), representing 20.4 per cent of the 108 traffic deaths listed during 1983. It should be noted that this is the same proportion as that seen in 1982 (Table 2). The 17 fatally injured motorcycle drivers were all male. Half of them were intoxicated at the time of fatal impact and approximately 75 per cent were not wearing helmets. The generalizations offered for the years 1977-1982 seem applicable to the 1983 experience.

married driver, the victims were either single or divorced. Four of the seven accidents took place either on Saturday or Sunday and most during the late spring or summer months. Four of the seven accidents occurred during daylight hours. Blood alcohol concentrations also were performed in four of the seven drivers involved in these overturn fatalities. Although a lengthy hospital stay precluded alcohol analysis in three of the fatalities, detectable alcohol was recorded in the remaining four cases. Only one of the victims wore a helmet at the time of the fatal impact.

Information concerning weather conditions, as determined by the amount of precipitation and degree of visibility, was analyzed. In none of these seven instances of overturn was there any precipitation during or immediately before the accident. Indeed, visibility was described as unimpaired or excellent in six of the accidents. During the seventh, a light fog was described (Table 8, Case 2).

Local weather conditions were studied for the dates and hours of the accidents resulting in the 97 motorcycle driver fatalities. There was no re-

corded precipitation at the time of 93.9 per cent of the accidents, light rain was noted in 3.7 per cent, and moderate rain in 2.4 per cent. The US Weather Bureau reported excellent visibility at the time of 86.6 per cent of the accidents, light haze in 2.4 per cent, and light fog in 11 per cent.

Table 9 summarizes data on the 12 motorcycle passengers who were fatally injured. Their average age was 20.9 years. Ten were unmarried, and almost all of the accidents took place over the weekend. Most of these accidents involved collision with other moving vehicles, and in only one instance (case 4) was the driver also killed.

In Rhode Island, 10.8 per cent of all men between the ages of 15 and 24 years are presently married.⁶ Among the fatally injured motorcycle drivers in the same age range, only 3.7 per cent were married. In Rhode Island males between 25-44 years of age, 73.0 per cent are currently married. Among the fatally injured motorcycle drivers in this age group, 51.4 per cent were married.

The listed occupations of the 97 fatally injured motorcycle drivers are as follows: blue-collar

Table 4. — Motorcycle Fatalities in Rhode Island (1977-1982): Month of Year

Month of year	1	2	3	4	5	6	7	8	9	10	11	12	Total
Rhode Island													
Motorcycle fatalities	0	0	3	8	12	18	15	20	11	9	1	0	97
Observed/expected*	0	0	0.4	1.0	1.5	2.2	1.9	2.5	1.4	1.1	0.1	0	
United States													
Motorcycle fatalities	132	183	274	444	548	663	701	726	504	343	231	125	4,874
Observed/expected*	0.3	0.5	0.7	1.1	1.3	1.6	1.7	1.8	1.2	0.8	0.6	0.3	
Nature of Fatal Impact (Rhode Island):													
Moving vehicle	0	0	2	4	6	9	4	5	5	7	1	0	43 (44.3%)
Fixed object	0	0	0	3	4	7	8	12	6	2	0	0	42 (43.3%)
Overturned	0	0	0	1	2	1	1	2	0	0	0	0	7 (7.2%)
Other/Unknown	0	0	1	0	0	1	2	1	0	0	0	0	5 (5.2%)
Total	0	0	3	8	12	18	15	20	11	9	1	0	97 (100%)

* An observed number divided by an expected number. The expected number is determined by assuming a random distribution of fatalities. Thus, for example, the 97 fatalities if randomly distributed indicates 8.1 expected fatalities per month. The O/E ratio for March then equals $4/8.1 = 0.5$.

Table 5. — Motorcycle fatalities in Rhode Island (1977-1982): Day of Week

	Sun	Mon	Tues	Wed	Thurs	Fri	Sat	Total
Motorcycle driver fatalities	22	16	11	10	11	11	16	97
Observed/expected*	1.6	1.2	0.8	0.7	0.8	0.8	1.2	
Hours of fatal accident								
0600-1159	1	2	1	0	0	3	3	10
1200-1759	6	5	4	4	4	2	4	29
1800-2359	10	3	5	5	5	3	3	34
2400-0559	5	6	1	1	2	3	6	24
Total	22	16	11	10	11	11	16	97
Percentage of positive blood alcohol†	72	55.5	41.7	45.5	15.4	54.5	50	
Percentage of blood alcohol ≥ 0.16 gm per cent	36	22.2	0	9.1	7.7	36.4	33.3	

* See footnote, table 4.

† Based only on cases where blood alcohol was determined.

Table 6. — Motorcycle Fatalities in Rhode Island (1977-1982): Hour of Day

Hour:	2400-0559	0600-1159	1200-1759	1800-2359	Total
Motorcycle driver fatalities	24	10	29	34	97
Nature of impact:					
Other moving vehicle	6	5	13	19	43
Fixed object	15	4	10	13	42
Overtaken	2	1	3	1	7
Unknown	1	0	3	1	5
Percentage of positive blood alcohol*	70	0	25	58.1	
Percentage of blood alcohol ≥ 0.16 gm per cent	40	0	25	19.4	

* Based only on cases where blood alcohol was determined.

work, 34; managerial, 2; mercantile, 4; professional, 3; unemployed, 11; student, 16; and unknown or unstated, 27.

Discussion

The motorcycle represents a greater hazard to both drivers and passengers than does the conventional four-wheeled vehicle. In 1981, for example, 64.6 per cent of all motorcycle accidents reported to the Rhode Island police resulted in personal injury, and 6.9 per cent of these injuries were fatal.⁷ Nationally, 10.4 per cent of automobile accidents cause reportable personal injury and in 2.8 per cent of these events, the injury is fatal. The probability of injury and the likelihood of lethal outcome among the injured victims are substantially greater for the users of motorcycles when compared with those who use conventional automobiles.

In its 1980 report on fatal accidents, the National Highway Traffic Safety Administration characterizes the typical motorcycle fatality scenario:²

In urban areas, the accident occurs on a local street or possibly on a traffic way whose class is other than state route. The speed limit is between 30 and 45 mph. In rural areas, the speed limit tends to be 55 mph on other state routes or county roads. The time is between 4 pm and 4 am, usually on a Friday, Saturday or Sunday. A 16-35 year old male cyclist (usually 16-25 years old) is riding on this roadway. When it is known whether or not he is wearing a helmet, he usually is not.

When his accident occurs, it is not simply a matter of his falling from the bike or overturning — rather, there is a collision with another motor vehicle in transport. The danger does not come from a blind side or from behind, but is in front of the cyclist. Either the cyclist failed to recognize the hazard or someone failed to see the cyclist.

It doesn't appear to have been the weather. About 95 per cent of motorcycle accidents take place under normal atmospheric conditions. Almost as many take place during daylight conditions as during dark or dark but lighted conditions.

While the circumstances leading to the 97 motorcycle driver fatalities on Rhode Island roads and highways cannot be reduced to a single

etiologic profile, there is some merit in emphasizing those features which appear consistently in these deaths. In the overwhelming majority of accidents, for example, the fatally injured Rhode Island motorcycle driver is a white male, younger than 23 years of age, unmarried, and more often than not a blue-collar worker (48.6 per cent) or is unemployed (15.7 per cent). The fatal event occurs more commonly in the summer, especially in August, and during weekends. While more fatal accidents occur after sunset, they are almost as frequently encountered during daylight hours. Rain or impaired visibility does not seem to be associated with these accidents. The nature of the impact in almost 90 per cent of instances is a collision with another moving vehicle or a fixed object such as a guardrail or a tree. In approximately 7 per cent of fatalities, the motorcycle overturns prior to collision, and in such instances high levels of blood alcohol and an absence of protective helmets are generally noted. Detectable concentrations of blood alcohol are described in more than half of all fatally injured drivers, and measurable blood alcohol is most commonly correlated with accidents occurring between midnight and 6 am and least commonly with accidents between sunrise and noon.

When these data are analyzed in terms of the separate variables, a problem of interpretation emerges. It appears that those factors generally held responsible for increasing the risk of motorcycle driver fatalities (eg, alcohol, or psychoactive drug use, or both; absence of protective helmet; and recreational use of the vehicle) are indeed nonrandomly associated with the night-time, weekend fatalities. In fatal accidents which occur during the weekday mornings, the drivers appear to be more prudent, at least as judged by their avoiding alcohol or psychoactive drugs and wearing helmets. At first glance, this latter group has fewer safety encumbrances and would seem to be the poorer drivers. We cannot

Table 7. — Motorcycle Fatalities in Rhode Island (1977-1982): Wearing Protective Helmet by Driver at Time of Fatal Accident*

Hour of day	2400-0559	0600-1159	1200-1759	1800-2359	Percentage Wearing helmet
Years of age					
15-24 (yes)	2	2	4	6	42.4
15-24 (no)	4	1	5	9	
24-34 (yes)	1	2	0	1	20.0
24-34 (no)	6	0	0	10	
35 and over (yes)	0	1	1	1	75.0
35 and over (no)	0	1	0	0	
Total percentage wearing helmet	23.1	71.4	50.0	29.6	

* Records of whether the motorcycle driver was or was not wearing a protective helmet at the time of the fatal accident were found in 57 of the 97 motorcycle driver fatalities.

Table 8. — Motorcycle Fatalities in Rhode Island (1977-1982): Instances of Vehicle Overturn with Driver Fatality

Number	Age and Sex	Marital Status	Time of Accident			Weather Condition†	Blood Alcohol (gm per cent)	Helmet Worn
			Month	Day	Hour*			
1	23 male	single	5	Sat	1656	none/good	not done‡	no
2	33 male	married	7	Sat	0830	none/light fog	not done	no
3	19 male	single	4	Thurs	1749	none/good	not done	yes
4	33 male	single	6	Sun	2207	none/good	0.36	no
5	34 male	divorced	8	Fri	0056	none/good	0.26	no
6	23 male	single	8	Tues	1438	none/good	0.03	no
7	20 male	divorced	5	Sun	0025	none/good	0.06	no

* Hour indicated with 24 hour clock

† Weather condition defined in terms of precipitation/visibility.

‡ Lengthy hospital stay precluded blood alcohol analysis.

Table 9. — Motorcycle Fatalities in Rhode Island (1977-1982): Fatally Injured Passengers

Number	Age and Sex	Marital Status	Blood Alcohol gm per cent	Day	Hour	Helmet	Comment
1	29 Female	single	0	Sun	2144	—	Passenger fell off
2	20 Female	single	0.18	Sat	1743	+	Motorcycle/moving vehicle
3	18 Female	single	?	Sat	0130	—	Motorcycle/moving vehicle
4	15 Female	single	0.15	Sun	1829	+	Motorcycle/moving vehicle; Driver also killed
5	20 Male	single	0.11	Tues	0129	+	Motorcycle/fixed object
6	21 Male	single	0	Fri	1800	?	Motorcycle/moving vehicle
7	20 Female	single	0.12	Sat	2400	?	?
8	19 Male	single	0.09	Mon	0100	?	Motorcycle/fixed object
9	29 Male	widowed	0.11	Mon	0100	?	Motorcycle/moving vehicle
10	18 Female	single	0	Sun	1300	—	Motorcycle/moving vehicle
11	18 Female	single	0.10	Tues	0034	—	Motorcycle/moving vehicle
12	24 Male	married	0.13	Sun	0102	—	Motorcycle/moving vehicle

reach any conclusions, however, until we are provided with information concerning the entire motorcycle driver population at risk. How many motorcycles, for example, are actively used during each weekday or weekend hour of the day and night? What percentage of motorcycle drivers, either accident-free or involved in nonfatal accidents, has detectable blood alcohol or psychoactive drug levels? What percentage of motorcycle drivers who are accident-free or involved in nonfatal accidents wears protective helmets? What percentage of motorcycle drivers not involved in fatal accidents is married, employed as blue collar workers or students, or is unemployed? Until appropriate denominators are established for the numerator data summarized in this paper, traffic fatality information expressed as rates cannot be generated.

There is little debate that the typical fatally

injured motorcycle driver conforms to a certain anecdotal stereotype. Until further information is available concerning the entire motorcycle driver population, we cannot conclude that these specified risk factors represent anything more than the demographic characteristics of the entire motorcycle driver population.

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- ⁴ Nakabayashi K, Aronson SC, Siegel M, et al: Traffic fatalities in Rhode Island. Part I: Descriptive epidemiology. *RI Med J* 67(1):25-30, 1984.
- ⁵ Nakabayashi K, Aronson SC, Siegel M, et al: Traffic fatalities in Rhode Island. Part II: The timing of accidents and the role of marital status, alcohol, and psychoactive drugs. *RI Med J* 67(4):171-178, 1984.

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The ban on using the pesticide ethylene dibromide (EDB) to fumigate grain should be lifted, and the proposed ban of its use on fruit postponed, until and unless a suitable replacement is found, according to a recent report from the American Council on Science and Health (ACSH). The independent, non-profit organization contends that while the potential health manifestations of EDB are "purely hypothetical," its benefits in protecting supplies of grain and fruit from insect contamination and destruction are demonstrable and significant.

According to the ACSH report *Ethylene Dibromide*, a person would have to eat at least "250,000 times as much food as normally consumed" to equal the cancer-causing dose of EDB given to laboratory animals. Studies have found that workers heavily exposed to EDB do not experience higher cancer rates than does the general public. Moreover, the EDB ban poses greater dangers for these workers as two of the three alternative fumigants are known carcinogens and the third is highly flammable. Other safer alternatives, such as cold treatment of fruit and gamma-irradiation, currently cannot be used because of inadequate facilities and the pending government approval of the irradiation process which is expected later this year.

• • •

A continuing medical education program developed by CME, Inc and the University of Washington School of Medicine is now available for physicians who have access to a personal computer. The initial curriculum includes 12 clinical simulation cases covering general medicine, pediatrics, obstetrics, and gynecology. Two hours of Category 1 credit toward the Physician's Recognition Award have been authorized for each case. Additional information is available from CME, Inc, PO Box 85655, Seattle, Washington 98145.

• • •

Data released by the American Medical Association reveal that women represent a growing proportion of the medical profession. From 1970 to 1981, the percentage of female physicians increased from 7.7 per cent to 12.2 per cent.

Career choice differences between female and male physicians are apparent in the type of specialty, the type of practice, and the hours worked each week. The average number of patient visits per week and both annual and hourly income rates also differ for male and female physicians, according to the 1982 statistics. While female physicians constituted 12.2 per cent of all doctors in 1982, they comprised smaller percentages of general and family practitioners (8.9 per cent) and surgeons (5.6 per cent), but larger percentages of medical and other specialists (15.4 per cent and 15.1 per cent respectively). Female physicians were more likely to be salaried than men. The proportion of self-employed female physicians was 26.4 per cent smaller than that of male physicians. One factor causing this difference may be the relatively larger proportion of young women in medicine as physicians 40 years of age or younger are less likely to be self-employed. Female doctors averaged 7.9 fewer hours in practice each week and saw 18.5 per cent fewer patients. Although these differences generally are not attributable to age and specialty distribution, the hours worked by men and women surgeons were nearly the same.

Female physicians, on the average, earn less from medical practice. Although part of the income differential may be traced to the hours practiced, specialty, and the form of practice, women physicians earned 75.6 per cent of the men's hourly average income. The comparable figure for the entire labor force is 59.1 per cent.

• • •

According to a report in the May 1984 issue of the *Archives of General Psychiatry*, the aggressive classroom activities of hyperactive children can be modified by behavior therapy. Many of the other deficits associated with hyperactivity, however, remain untouched by treatment. Researchers from the Columbia University College of Physicians and Surgeons evaluated the behavior of 28 identified hyperactive children during an eight-week period. Youngsters were randomly assigned to three groups, the first receiving methylphenidate, the second methylphenidate and behavior therapy, and the third behavior therapy with a placebo. Parents and teachers were instructed on methods of behavior modification, and each hyperactive child was paired with a same-sex classmate as a control.

Before treatment, the hyperactive children

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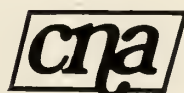
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demonstrated significantly more problem behavior than their normal peers, manifesting such signs as excessive physical activity, distractibility, and lack of cooperation and task involvement. The average pretreatment aggression score of one group of seven hyperactive children was 1.74, compared with a score of 0.19 for the control cohort. After eight weeks, the means for the two groups were 0.36 and 0.17 respectively. The researchers found, however, that although the levels of aggression were maintained in the hyperactive children with continued treatment, the other therapy objectives, including increased cooperation and interest in tasks, were not sustained.

• • •

The hand-held breath alcohol analyzer provides an accurate means of assessing emergency patients with suspected alcohol intoxication, according to a report in the July *Annals of Emergency Medicine*. Used primarily for the detection of intoxicated automobile drivers, these breath analyzers also have been utilized in drug and alcohol treatment programs and in pre-employment screening programs. In a series of patients with concussions in the emergency department, approximately 40 per cent had been drinking and the blood alcohol levels in 36 per cent were greater than 0.10, the legal definition of intoxication in most states. Thirty per cent of the adolescent drivers involved in automobile accidents had been drinking before the accident. Many of these emergency patients also had associated problems, including head injury, multiple trauma, metabolic disturbances, drug overdose, behavioral emergencies, or coma.

• • •

The American Cancer Society (ACS) recently published dietary guidelines as part of a special report, *Nutrition and Cancer: Causes and Prevention*. The organization suggests maintenance of optimal weight; reduction of total fat consumption; consumption of high-fiber foods, foods rich in vitamins A and C, and such cruciferous vegetables as cabbage and broccoli; and reduction of salt-cured, smoked, and nitrate-cured foods. In addition, the ACS recommends that persons moderate their consumption of alcoholic beverages.

Without making specific recommendations, the ACS report also comments on the impact of

food additives. While noting that the current level of knowledge concerning the potential carcinogenic effects of food additives is inadequate to warrant a recommendation, the report comments that those additives which have been found to cause cancer already have been banned. Moreover, it notes, "some others may protect against the disease."

The hypothesis that diet may play a significant role in the etiology and prevention of cancer recently has been the subject of substantial publicity. Current estimates are that some 35 per cent of cancers in the United States may be attributable to dietary factors.

• • •

The New York City Poison Control Center recently reported a significant increase in the number of cases of vitamin B6 (pyridoxine) toxicity. According to a bulletin from the New York City Department of Health, it is now known that megadoses of the vitamin are responsible for a newly-recognized peripheral sensory neuropathy. Prior to 1983, water-soluble vitamins were not thought to be toxic since excessive amounts ingested are excreted through the kidneys. One of the adverse reactions from pyridoxine megadoses, however, includes a gait disorder, which may result in an inability to walk, and impairment of the sensations of touch, vibration, pain, and temperature.

Pyridoxine has gained wide acceptance by naturalists and health food advocates as a component needed for body building and as a remedy for premenstrual tension and edema. Twenty to 1,000 times the recommended daily dietary allowance frequency is recommended by its advocates. Because of this publicity concerning the alleged benefits of vitamin B6, the department cautions clinicians to "consider pyridoxine megadoses among the etiologies for the patient presenting with a peripheral sensory neuropathy."

Another dietary supplement of recent concern is selenium. It is widely distributed in the soil, forages, and grains, and has numerous commercial uses. Human ingestion of the element comes primarily from cereal, fish, and meat. While there is no established recommended daily allowance, the proposed adequate and safe intake of selenium in adults is 50-200 mcg daily. The Centers for Disease Control recently reported one case of selenium poisoning which evidently resulted from a defective lot of a selenium supplement. ■

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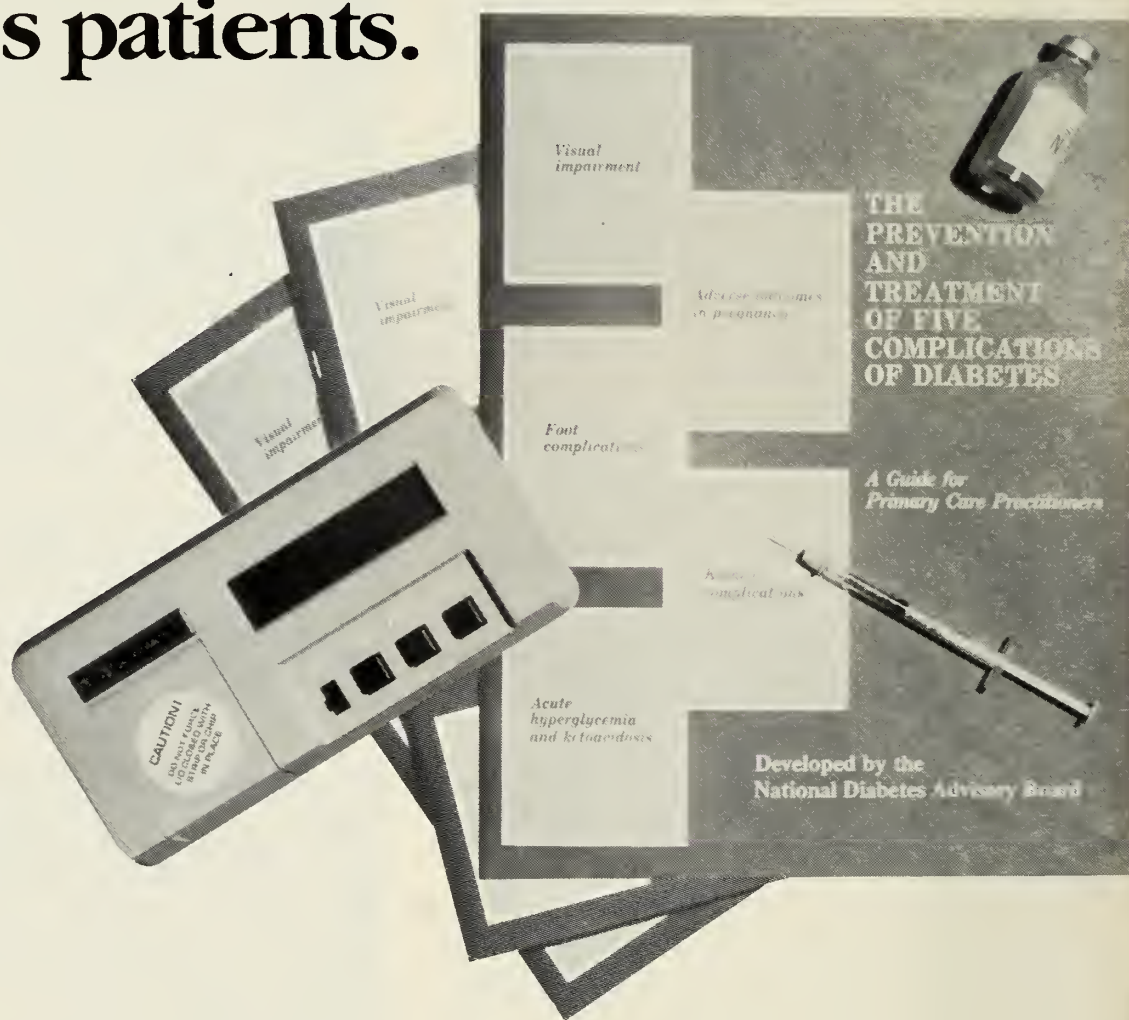
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Drug interactions. Aspirin, used concomitantly may decrease *Motrin* blood levels.

Coumarin bleeding has been reported in patients taking *Motrin* and coumarin.

Pregnancy and nursing mothers: *Motrin* should not be taken during pregnancy or by nursing mothers.

Adverse Reactions: The most frequent type of adverse reaction occurring with *Motrin* is gastrointestinal of which one or more occurred in 4% to 16% of the patients.

Incidence Greater than 1% (but less than 3%)—Probable Causal Relationship

Gastrointestinal: Nausea,* epigastric pain,* heartburn,* diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence); **Central Nervous System:** Dizziness,* headache, nervousness; **Dermatologic:** Rash* (including maculopapular type), pruritus; **Special Senses:** Tinnitus; **Metabolic/Endocrine:** Decreased appetite; **Cardiovascular:** Edema, fluid retention (generally responds promptly to drug discontinuation, see PRECAUTIONS).

Incidence less than 1%—Probable Causal Relationship**

Gastrointestinal: Gastric or duodenal ulcer with bleeding and/or perforation, gastrointestinal hemorrhage, melena, gastritis, hepatitis, jaundice, abnormal liver function tests; **Central Nervous System:** Depression, insomnia, confusion, emotional lability, somnolence, aseptic meningitis with fever and coma; **Dermatologic:** Vesiculobullous eruptions, urticaria, erythema multiforme, Stevens-Johnson syndrome, alopecia; **Special Senses:** Hearing loss, amblyopia (blurred and/or diminished vision, scotomata, and/or changes in color vision) (see PRECAUTIONS); **Hematologic:** Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia (sometimes Coombs positive), thrombocytopenia with or without purpura, eosinophilia, decreases in hemoglobin and hematocrit; **Cardiovascular:** Congestive heart failure in patients with marginal cardiac function, elevated blood pressure, palpitations; **Allergic:** Syndrome of abdominal pain, fever, chills, nausea and vomiting, anaphylaxis, bronchospasm (see CONTRAINDICATIONS); **Renal:** Acute renal failure in patients with pre-existing significantly impaired renal function, decreased creatinine clearance, polyuria, azotemia, cystitis, hematuria; **Miscellaneous:** Dry eyes and mouth, gingival ulcer, rhinitis.

Incidence less than 1%—Causal Relationship Unknown**

Gastrointestinal: Pancreatitis; **Central Nervous System:** Paresthesias, hallucinations, dream abnormalities, pseudotumor cerebri; **Dermatologic:** Toxic epidermal necrolysis, photoallergic skin reactions; **Special Senses:** Conjunctivitis, diplopia, optic neuritis; **Hematologic:** Bleeding episodes (e.g. epistaxis, menorrhagia); **Metabolic/Endocrine:** Gynecomastia, hypoglycemic reaction; **Cardiovascular:** Arrhythmias (sinus tachycardia, sinus bradycardia); **Allergic:** Serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis; **Renal:** Renal papillary necrosis.

*Reactions occurring in 3% to 9% of patients treated with *Motrin*. (Those reactions occurring in less than 3% of the patients are unmarked.)

**Reactions are classified under "Probable Causal Relationship (PCR)" if there has been one positive rechallenge or if three or more cases occur which might be causally related. Reactions are classified under "Causal Relationship Unknown" if seven or more events have been reported but the criteria for PCR have not been met.

Overdosage: In cases of acute overdosage, the stomach should be emptied. The drug is acidic and excreted in the urine so alkaline diuresis may be beneficial.

Dosage and Administration: Rheumatoid arthritis and osteoarthritis. Suggested dosage is 300, 400, or 600 mg t.i.d. or q.i.d. Do not exceed 2400 mg per day. Mild to moderate pain, 400 mg every 4 to 6 hours as necessary.

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WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Anti-hypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances, postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

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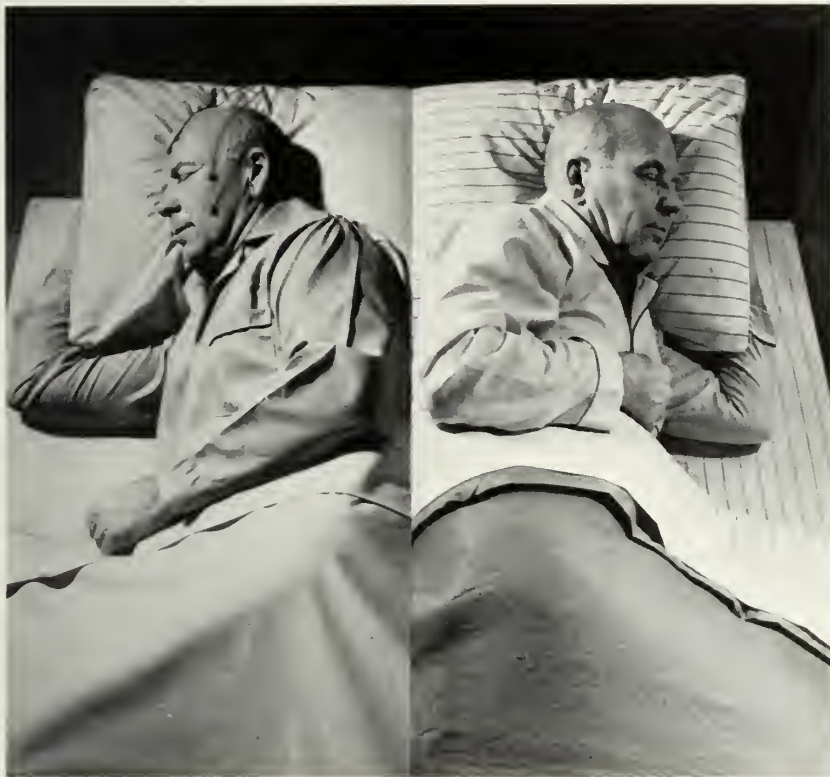
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References: 1. Kales J et al: *Clin Pharmacol Ther* 12:691-697, Jul-Aug 1971. 2. Kales A et al: *Clin Pharmacol Ther* 18:356-363, Sep 1975. 3. Kales A et al: *Clin Pharmacol Ther* 19:576-583, May 1976. 4. Kales A et al: *Clin Pharmacol Ther* 32:781-788, Dec 1982. 5. Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. 6. Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. 7. Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther* 27:355-361, Mar 1977. 8. Zimmerman AM: *Curr Ther Res* 13:18-22, Jan 1971. 9. Amrein R et al: *Drugs Exp Clin Res* 9(1):85-99, 1983. 10. Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. 11. Greenblatt DJ et al: *Sleep* 5(Suppl 1):S18-S27, 1982. 12. Kales A et al: *Pharmacology* 26:121-137, 1983.

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Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, light-headedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

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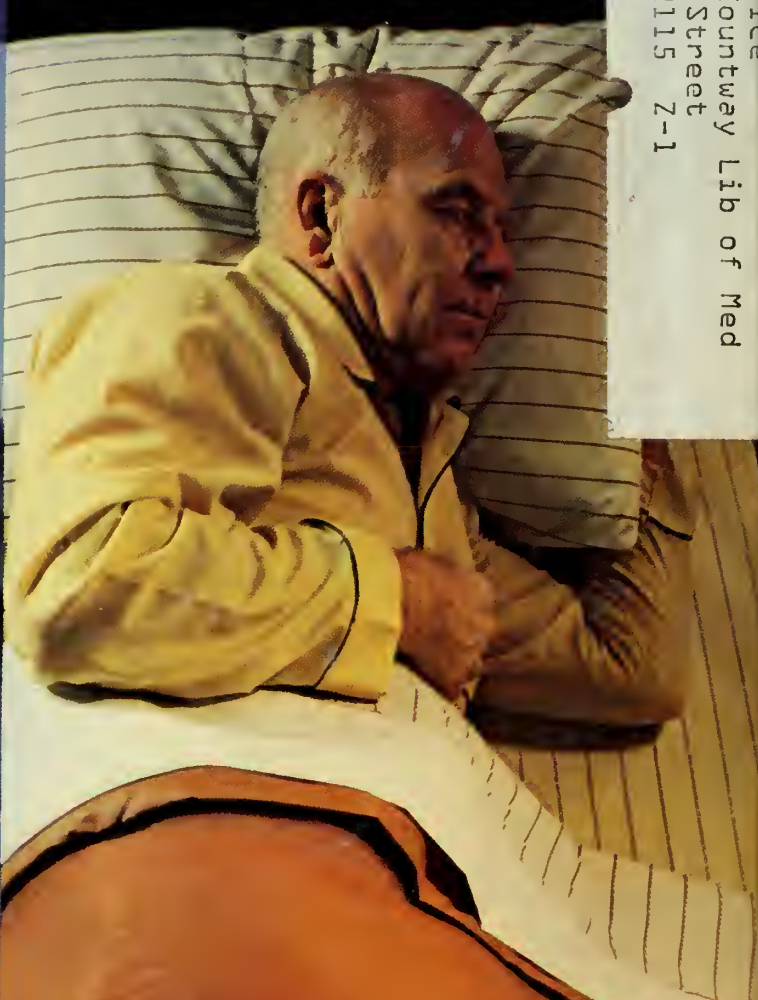
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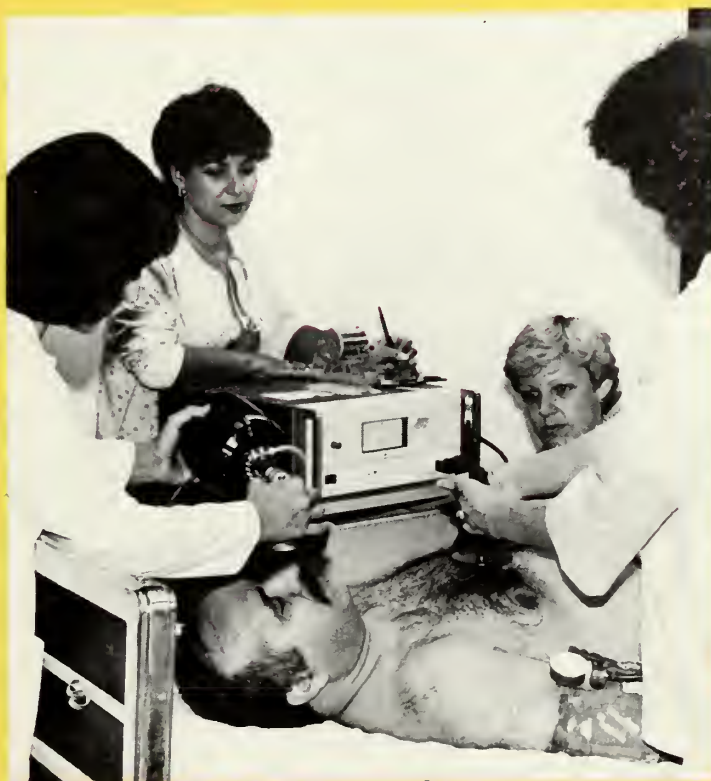
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Rhode Island

**DISPLAY
SHELVES**

November 1984
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Medical Journal



Advanced Life Support
in Rhode Island — See page 477

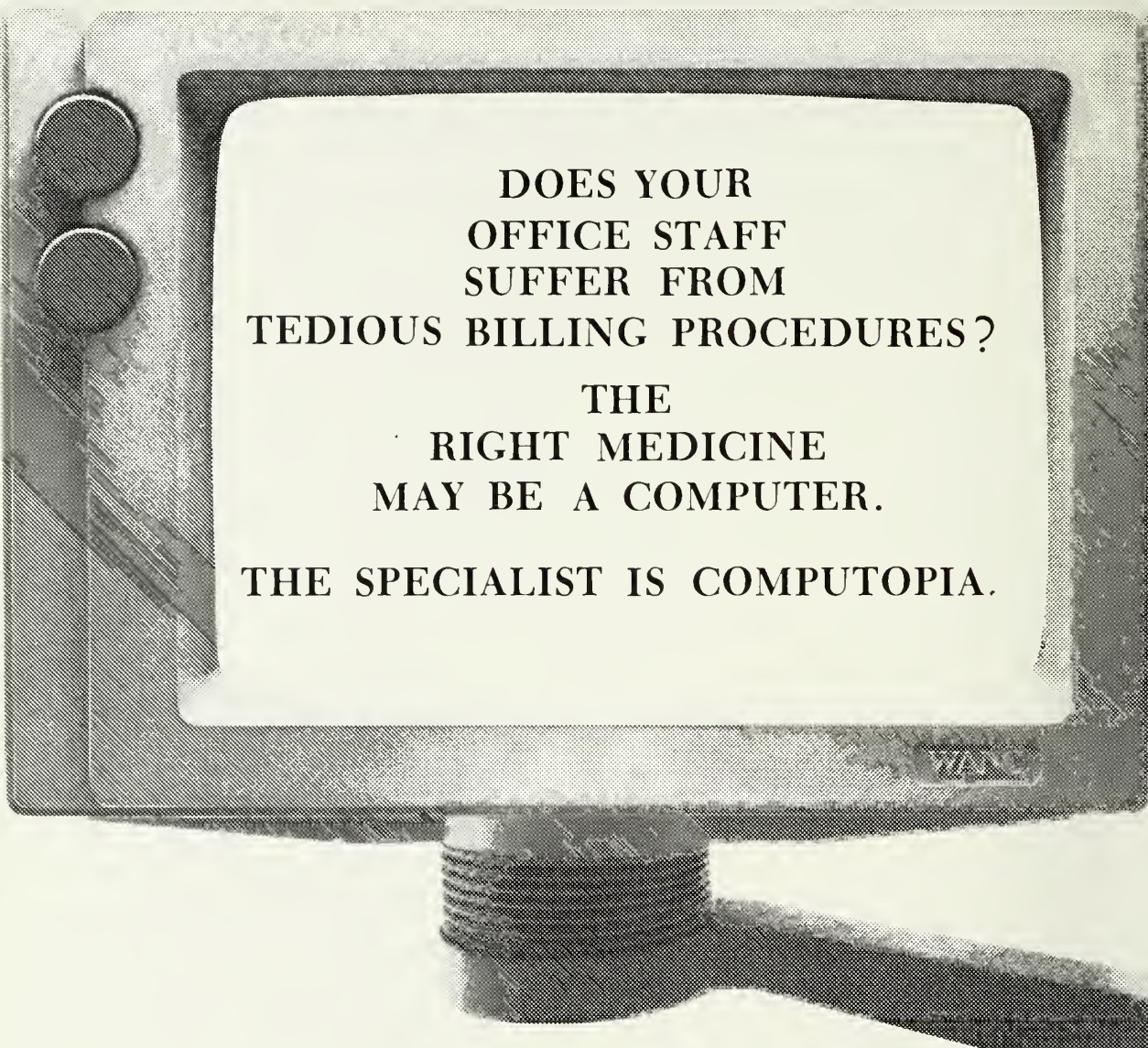
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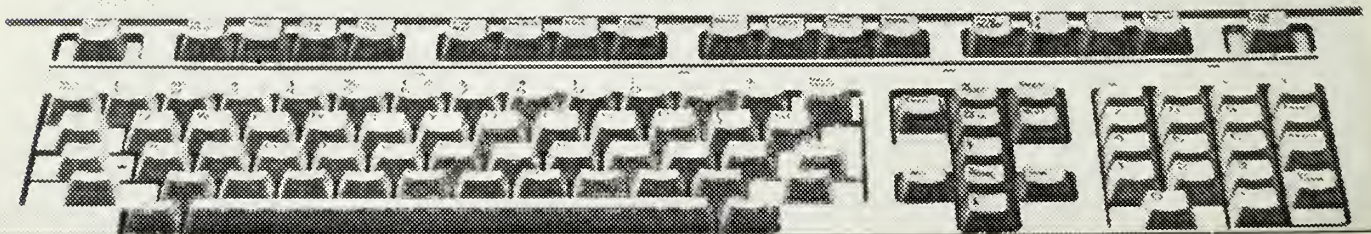
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FEDERAL COURT RULES ON MEDICARE FREEZE

In late September the federal district court in Indianapolis extended the deadline for deciding whether to sign up as a participating physician under the Medicare amendments to the Deficit Reduction Act of 1984. The two-week postponement from October 1 to October 15 applied to those members of the American Medical Association and the Indiana State Medical Association who had not received copies of their charge profiles from Medicare fiscal intermediaries by September 28.

At issue were provisions of the law which: 1) freeze physician reimbursement under the Medicare program from July 1, 1984 until September 30, 1985; 2) create a new class of "participating physicians," ie, those who agree to accept assignment of Medicare benefits as payment in full for all Medicare patients; and 3) require close federal scrutiny of all claims submitted by non-participating physicians.

The AMA is seeking a permanent injunction against implementation of the law, contending that it violates the 14th amendment by discriminating against physicians and creating two classes of Medicare beneficiaries. The Deficit Reduction Act prohibits non-participating physicians from increasing their charges during the freeze. Moreover, the act "clearly violates" the Medicare law, according to the AMA, which guarantees equal treatment of beneficiaries regardless of their choice of physician.

The AMA is actively pursuing the constitutional issues raised by the freeze in federal court. At its September 19 meeting, the RIMS House of Delegates had authorized the Society to investigate the feasibility of seeking an injunction on its own initiative if the AMA decided against doing so. The RIMS resolution was made moot by the AMA's subsequent actions.

In a related development, preliminary data indicate that only 65,000 physicians, out of a potential 500,000, had signed participa-

FEE FREEZE (continued)

tion contracts with their Medicare intermediaries by September 28. The numbers across the nation range from three per cent in Alaska to 28 per cent in Vermont.

SOCIETY SPONSORS MEETING WITH DI PRETE

The escalating malpractice crisis again dominated the agenda at an October 17 breakfast meeting with the Republican gubernatorial candidate, Mayor Edward DiPrete of Cranston. More than 40 RIMS members and their guests attended the third in a series of meetings with the candidates for the post. Earlier this fall, breakfasts were held with the Democratic contenders, Mayor Joe Walsh of Warwick and state treasurer Anthony Solomon.

In response to a question concerning the malpractice commission created by the RI General Assembly earlier this year, DiPrete said that he would require commissions to file interim and final reports. In general, however, he noted his aversion to commissions and ad hoc committees to address the state's problems unless they were "absolutely essential."

Other topics covered at the two-hour meeting included proposals by Rhode Island optometrists to use therapeutic drugs for ocular disease, the availability and cost of health care to the elderly, and health planning with particular attention to the Statewide Health Coordinating Council.

SOCIETY RECOMMENDS CHANGES TO THE BOARD OF MEDICAL REVIEW

At its October 15 meeting, the RIMS Council accepted the report of a subcommittee appointed earlier this year to "review the fairness of procedures employed by the Board of Medical Review in investigating alleged cases of unprofessional conduct." The Board was established by the General Assembly in 1976 as the "watchdog agency" for the state's physicians. After review-

BOARD OF MEDICAL REVIEW (continued)

ing the Board's handling of a case involving a RIMS member, the subcommittee tried to identify areas where the hearing process could be made more equitable.

Concerns had been expressed by some RIMS members about cases initiated by the Board on its own authority. While reports may be received from such sources as patient complaints, insurance company and JUA settlements, and hospital disciplinary actions, the Board also is authorized by statute to investigate physicians on its own initiative. Under procedural rules adopted by the agency, the physician must be notified when a written complaint is received. The operating guidelines, however, do not address the issue of notification when the Board starts an investigation on its own.

The recommendations accepted by the Council include:

- "The basis on which the Board will initiate an investigation on its own accord should be defined and circumscribed to avoid infringing on a physician's right to exercise professional discretion in treating patients and inhibiting the use of new medical procedures;
- "When the Board initiates an investigation on its own, the subject physician should be notified of the investigation as soon as the matter is referred to a hearing committee;
- "The statutory definition of unprofessional conduct as it relates to overutilization should be strictly construed and charges of overutilization should be precisely limited to those acts outlined in the statute; and
- "The Board should clarify the role of any physician appointed by it to conduct an investigation in order to insure that the investigating physician only develops information on which the Board can act and the Board forms its own opinion as to whether there has been unprofessional conduct."

Members of the subcommittee included John H. Reid, III, the Society's legal counsel from Edwards & Angell; and Drs Herbert Rakatansky, Charles Hall, and William Varr, Jr.

HEALTH CARE REVIEW AGREES TO STUDY CONTROVERSIAL PROGRAM

As the result of a meeting with Society representatives, officials of Health Care Review, Inc., the professional review organization (PRO) for Rhode Island, have agreed to study 18 surgical procedures proposed under a controversial "pre-admission" review program mandated by the federal government. Effective October 1, Health Care Review required that all elective inpatient admissions of Medicare beneficiaries be reviewed for approximately 100 surgical procedures. The PRO contends that the operations may be performed safely on an outpatient basis for most patients. In order for the patient to receive Medicare reimbursement for hospital services, however, the physician must obtain prior approval from the PRO.

The list of so-called "outpatient procedures" was produced locally from an earlier compilation of 72 procedures previously submitted by state subspecialty societies to the PRO's predecessor organization, the Rhode Island Professional Standards Review Organization (RIPRO), and some 70 operations recommended by the federal Health Care Financing Administration. Local PROs were granted limited authority to deviate from the national guidelines.

After a September 26 meeting between a RIMS ad hoc committee headed by Dr Richard Wong and officers of Health Care Review, the PRO agreed to delete 18 procedures from the list pending additional study by the affected subspecialty societies concerning whether they may be performed safely on outpatients. Health Care Review also agreed to develop an expedited procedure for cases in which the patient is to be hospitalized within one or two days of the physician's request for approval.

Meanwhile, it has been reported that Health Care Review, Inc. applied for the peer review contracts in Maine and Connecticut. All hospitals must sign contracts with their peer review organizations by November 15 to receive Medicare reimbursement.

RIMS REPRESENTED AT NATIONAL CONFERENCE

President Dr Paul J.M. Healey and Walter Cotter represented the Society at a national conference on professional liability held in late September by the Council

MALPRACTICE CONFERENCE (continued)

of Medical Specialty Societies (CMSS). One of the objectives of the meeting was to "generate support for malpractice reform by emphasizing the negative influences of professional liability on health care costs and the physician/patient relationship." The two-day meeting featured such keynote speakers as Dr James Todd, AMA Trustee and President of the Physician Insurers Association of America; William J. Curran, JD, LLM, Harvard Medical School and New England Journal of Medicine; and representatives of 12 national specialty societies, some of which have established their own insurance programs.

Among the significant findings reported at the CMSS conference, according to Drs Healey and Cotter, were:

- Unlike the 1975-1976 malpractice crisis in which the predominant problem was the availability of insurance, the current situation involves whether physicians can afford the premiums. Some high-risk specialists currently are paying more than \$100,000 annually in Florida and New York.
- While physician-controlled carriers currently insure more than half of the nation's physicians, their premiums also are escalating because of the increasing number of suits filed and larger settlements and awards.
- Some comparatively low-risk specialties, such as ophthalmology and psychiatry, have established their own insurance programs to avoid underwriting the insurance costs of the higher risk specialties.
- Despite the introduction of HR 5400, the Alternative Medical Liability Act, by Reps Richard Gephardt (R, MO) and Henson Moore (D, LA), the extent of federal involvement in malpractice reform has been minimal. This "hands-off" attitude may well change because of the impact of the costs of defensive medicine, now estimated to reach some \$100 billion annually.
- Professor Curran told conference participants that effective malpractice reform legislation must include the

TORT REFORM (continued)

following components: efficient screening panels, early settlement of claims, and a system of structured awards and settlement costs. Cited as an example of one approach was a series of reforms initiated in California which include such features as reduction in the statute of limitations to one year, a limitation on awards for "pain and suffering" to \$100,000, mandatory disclosure of collateral sources, and a declining contingency scale for attorneys.

In Rhode Island, the malpractice commission authorized by the General Assembly earlier this year must publish its recommendations by February 1. The Rhode Island Medical Society Foundation also plans a series of newspaper and media advertisements to stimulate public awareness of the malpractice crisis and its negative effects on patients. Also under consideration by the Foundation is presentation of seminars on tort reform and risk management in office and hospital practice.

PERIPATETICS

Rhode Island physicians in the news include:

- Dr Israel Diamond, Chairman, Department of Pathology, Roger Williams General Hospital, has received the Presidential Award Medal of the College of American Pathologists. The award was presented in recognition of his 25 years of service to the College. Dr Diamond also has been named to the editorial board of the Archives of Pathology and Laboratory Medicine.
- Recently named president of the Rhode Island Chapter of the American College of Surgeons was Providence surgeon Dr John Stuart.
- Governor J. Joseph Garrahy recently appointed Providence pediatrician Dr Betty Mathieu to the RI Advisory Council on Women. Dr Mathieu also serves as chairperson of the RIMS Child School Health Committee.
- Dr Edwin N. Forman, Providence, was named president of the American Cancer Society, RI Division, at its recent annual meeting. Dr Francis J. Cummings, also from Providence, was elected vice-president.

PRACTICE MANAGEMENT QUESTION OF THE MONTH

THROUGH THE MEDICARE MAZE: THE FEE FREEZE AND LABORATORY TESTS

In addition to freezing physician reimbursement under Medicare, the Deficit Reduction Act of 1984 requires significant changes in the way that the Medicare program will pay for clinical diagnostic laboratory tests. The law, retroactive to July 1, calls for substantially-reduced payment levels and a national fee schedule by 1987. Reimbursement levels will vary widely depending on whether the patient is hospitalized and where the test is performed.

LABORATORIES IN PHYSICIANS' OFFICES: Effective July 1, fee schedules for laboratory services reimbursement under Medicare Part B (physicians' services) will be established at 60 per cent of the prevailing charge permitted on June 30, 1984. This applies whether the test is performed in the physician's office or sent to an independent clinical laboratory.

Physicians will be reimbursed for tests performed in their offices only if they perform or supervise the performance of the test. Payments also will be made to a doctor sharing a practice with a physician who performs or supervises the test. The reimbursement levels, however, are different for "participating" and "non-participating" physicians. If the physician "participates" in the Medicare program and accepts the reimbursement as payment in full, Medicare will pay 100 per cent of the allowed charge (defined as 60 per cent of the June 30, 1984 prevailing charge). If the physician bills the patient directly, Medicare will reimburse the patient only 80 per cent of the allowed amount.

Drawing and handling charges: One provision of the new law may create special problems for physicians who collect specimens and send them to independent laboratories for processing. Between 1979 and 1984, the "drawing and handling" fee was limited to \$3 for packaging and processing a specimen. This limitation has been a source of continuous frustration for many physicians since the \$3 fee barely covers the cost of the insurance paperwork generated by the specimen in most cases. Under the new law, physicians will be permitted to continue charging a "nominal" fee for drawing and handling specimens. While previously a separate fee could be charged for each specimen, the new law permits only one collection fee for each patient encounter during which specimens are drawn.

HOSPITAL LABORATORIES: All hospital laboratories must accept the Medicare reimbursement as payment in full for both ambulatory and inpatient diagnostic tests. For outpatients, the fee schedule for tests performed by a hospital laboratory will be 62 per cent of the prevailing rate as of June 30, 1984. Under the prospective payment system already in place for most hospitals, the charges for laboratory tests performed for Medicare inpatients are not billed separately and are included as part of the DRG reimbursement level for that patient.

INDEPENDENT CLINICAL LABORATORIES: Free-standing clinical laboratories, ie, those which are independent of a physician's office or a rural health center, will be reimbursed at 60 per cent of the June 30, 1984 prevailing rate. Like hospital laboratories, these facilities must accept assignment of Medicare benefits as payment in full.

FEE SCHEDULES: For the three years beginning July 1, 1984, a fee schedule for laboratory services may be established on a statewide, regional, or carrier service area basis. A national fee schedule will become effective on July 1, 1987. Under the new law, the federal government also is authorized to "negotiate" fees at a level lower than those permitted under the fee schedule. Also of interest to physicians: The Department of Health and Human Services has been charged with investigating the feasibility of making direct payments to the physicians who ordered the laboratory tests.

Rhode Island Medical Journal

November 1984
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COVER

Nurses from the Artificial Kidney Center of Rhode Island performing advanced cardiac life support developed by the American Heart Association on Kenneth B. Linhares, Emergency Cardiac Care Coordinator, AHA Rhode Island Affiliate. Mr. Linhares is one of the contributors of a paper on this topic which begins on page 503.

Photograph provided courtesy of the Rhode Island Affiliate, American Heart Association, Pawtucket, Rhode Island.

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Traffic Fatalities Are No Accidents

The inner pages of the *Providence Journal Bulletin* provide us with the unadorned facts: "... a 19-year-old male from Providence was fatally injured when the car that he was driving collided with a tree at the intersection of . . ." The meager details of the news item indicate neither why this tragedy took place nor why this person and not someone else was involved.

During the past year, the *Rhode Island Medical Journal* has published four epidemiologic studies of the 766 traffic fatalities occurring within the state from 1977 through 1982. These papers have attempted to determine whether traffic fatalities are nonrandom events; whether, perhaps, there are measurable temporal and personal factors which make certain times more likely and certain persons more vulnerable to the morbidities and mortalities of automobile travel. These studies have offered the following observations:

- 1) About half of those killed in traffic accidents are males younger than 34 years of age, and these males are more commonly drivers. The fatally-injured females, on the other hand, are more often in a passive role (ie, passengers or pedestrians). In either sex, the active/passive status ratio diminishes beyond middle age.
- 2) While the number of traffic fatalities involving individuals older than 75 years is relatively small, the age-related mortality rates are in the same high range as the 15-34 year olds because the elderly population at risk is quite small.
- 3) Traffic fatalities occur much more commonly during weekends and especially during the hours of darkness.
- 4) Individuals who are either single, divorced, or separated are at substantially higher risk for fatal traffic accidents than those who are married.
- 5) A measurable level of blood alcohol is detected in more than 50 per cent of those involved in fatal accidents whether they are drivers, passengers, or even pedestrians. Alcohol is detected in the blood of virtually every accident victim killed between midnight and dawn.
- 6) In the case of fatally-injured motorcycle drivers, the overwhelming majority are white males, younger than 23 years of age, unmarried, and typically unemployed or working in manual labor. Rain or impaired visibility does not seem to be associated with these motorcycle accidents. On the other hand, high levels of blood alcohol and an absence of protective helmet usage are generally noted.
- 7) The typical male pedestrian victim in Rhode Island is in his thirties, unmarried or separated, without a job or employed as a blue collar worker, and is more often than not under the influence of alcohol at the time of the accident.
- 8) Fatalities involving elderly pedestrians tend to occur more commonly in winter months, especially when visibility is diminished. There is some anecdotal evidence suggesting that confusion, distraction, or even cognitive impairment may make certain elderly persons more vulnerable to pedestrian accidents.

What is the role of the medical profession in addressing this problem? The group most prone to traffic fatalities are the unmarried males be-

tween ages 16 and 25 years, who often mix alcohol and anger with the act of driving. Very few persons in this group are likely to be under active medical care before the accident, so that the expectation of any form of intervention by physicians is unrealistic.

There is, however, a group which bears more than its share of accident victims: the elderly. Indeed, as measured by risk of fatal accident per mile driven, the highest rates are generated by female drivers older than age 75 years. As pedestrians, the elderly are also uniquely vulnerable to fatal traffic accidents, especially during the winter months and twilight hours, times when the driver's acuity may be dulled by reduced visibility and enhanced blood alcohol concentrations.

It is certainly within the realm of our professional responsibility to urge that our elderly pa-

tients voluntarily relinquish their driver's licenses, especially when there is demonstrated impairment of their vision, hearing, hand-eye coordination, reaction time, or altered cognition. Similarly, the frail elderly patient should be repeatedly instructed in the rules of prudent pedestrian behavior.

Physicians frequently are scolded by the press for devoting inadequate attention to the prevention of disease. If we can identify those of our patients who are at particular risk for traffic injury, surely we are then obliged to develop special strategies which might avert these vehicular calamities. Of course, the daily newspapers will not publish instances of traffic accidents which, because of prior interventions by the practicing physician, never took place.

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PRESIDENT'S PAGE



HR 5400: The "No Fault" Approach to Medical Malpractice

Representative W. Henson Moore (D, Louisiana) is a political realist. His activities and inquiries have produced the first legislative proposal on the federal level which deals with the omnipresent medical liability problem. Together with Representative Richard Gephardt (R, Missouri), Moore introduced HR 5400, the Alternative Medical Liability Act, during the last session of Congress. While Moore and Gephardt certainly did not anticipate passage of the bill this year, their stated intention was to publicize the problem and its negative impact on the nation's health. Medical malpractice insurance and costs clearly have become a societal issue. Defensive medicine accounts for approximately one-third, or \$100 billion, of the national medical bill. Another \$3.5 billion is spent annually on malpractice premiums for physicians and hospitals. As the federal government is responsible for approximately 50 per cent of all health care costs, it is small wonder that Congress, in its search to brake "run-away health spending," has discovered one of the primary reasons for the escalation of these costs.

What does HR 5400 provide? What are its chances for passage in 1985?

The bill will affect all federally-financed medical programs, including Medicare, Medicaid, CHAMPUS, and VA programs. It will transfer incidents of medical maloccurrence from the current tort system to a form of no-fault coverage. Developed by William O'Connell of the University of Virginia, the author of "no-fault" automobile insurance, the law would provide for settling untoward medical incidents in a distinctly unique manner. The physician, hospital, or other health care provider may offer a settlement to the



Paul J. M. Healey, MD

injured patient within six months of its occurrence. The award would eliminate such non-economic losses as pain and suffering. For the patient, it would assure payment and prompt results. While currently only 18 per cent of the settlements awarded to plaintiffs actually reach the injured person and 82 per cent is absorbed by the legal system, HR 5400 would reverse that ratio. The proposed legislation also includes other features targeted at the initial goal, to eliminate a significant element of high-cost health care. Trial lawyers already have mounted an attack on the bill and Congressman Moore readily admits that the lawyers will make its passage difficult. In fact, he predicts only a 50 per cent chance of passage next year.

But the effort eventually may bring rewards to physicians and their patients in a way not yet evident, simply by focusing federal attention on a thorny problem. ■

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Traffic Fatalities in Rhode Island: Part IV

The Pedestrian Victim

Sarah C. Aronson, AB
Kemi Nakabayashi, AB
Michael Siegel
William Q. Sturner, MD
Stanley M. Aronson, MD

This paper describes and analyzes the 173 pedestrian deaths recorded by the Rhode Island Office of the Medical Examiner within the six-year interval of 1977-1982.¹⁻³ During this period, fatally-injured pedestrians represent 22.6 per cent of the registered 766 traffic fatalities.

The following information was recorded for each of these 173 deaths: age; sex; marital status; occupation; blood alcohol concentration; toxicologic analyses, including carbon monoxide; date of accident, including hour of day and day of week; and the type of involved vehicle. These variables were examined for non-random distributions as well as intervariable correlations. Occasionally, the findings were compared with census data describing the general population of Rhode Island.

A number of factors, in varying magnitude, contribute to the likelihood of pedestrian fatality: driver negligence, vehicular inadequacy, structural highway failure, poor visibility, and altered

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This and prior papers in this series represent undergraduate honors studies undertaken at Brown University by Sarah C. Aronson, Kemi Nakabayashi, and Michael Siegel. At the present time, Sarah C. Aronson is a medical student at Dartmouth Medical School; Kemi Nakabayashi is a medical student at Case-Western Reserve University; and Michael Siegel continues his undergraduate studies at Brown University. William Q. Sturner, MD, is Chief Medical Examiner, State of Rhode Island and Professor of Pathology, Brown University Program in Medicine. Stanley M. Aronson, MD, is University Professor of Medical Science, Brown University.

pedestrian behavior. Studies have shown, for example, that a significant fraction of fatally-injured pedestrians were on sidewalks, in safety zones, or were properly crossing the street with a green light at the time of the accident.⁴ When these accidents are analyzed critically, it appears that approximately 46 per cent of pedestrian fatalities are attributable to driver error. While neither lessening the responsibility of drivers nor the contribution of other measurable factors resulting in pedestrian injury, this paper nevertheless will focus only on the characteristics demonstrated by pedestrians in order to understand better those features which render them more vulnerable to traffic accidents.

Observations

Season and day of accident: Pedestrian fatalities are slightly more common during the autumn and winter months, accounting for about 59 per cent of the total number of pedestrian deaths in this series. This colder weather clustering is somewhat more apparent in the female pedestrian fatalities (Table 1) and in males older than 75 years of age (Table 3).

Pedestrian fatalities occur more frequently on weekends (Friday, Saturday, and Sunday). Slightly more than half of all fatalities in this series were on the weekend, especially Saturdays. This weekend clustering is more apparent in the summer and autumn.

There is no significant correlation between the season and the blood alcohol concentration levels of the pedestrian victims except during the winter months when the frequency of positive results is lower. This may reflect the selective vulnerability of the elderly to winter pedestrian fatalities, and alcohol consumption in this older population is substantially lower (Table 3).

Blood alcohol, in concentrations at or exceed-

ing 0.06 gm per cent, are recorded in approximately one of every three fatally-injured pedestrians older than 14 years of age.

Hour of accident: The data derived from the 173 pedestrian fatalities were reordered such that the hour of the accident became the independent variable (Table 2). Each death was assigned to one of four six-hour intervals of the day. The greatest concentration of deaths is noted between 8 pm and midnight, while the fewest are encountered between 6 am and noon. Male deaths dominate the interval between midnight and 6 am, representing 77.8 per cent of fatalities during these hours, while the afternoon hours, from noon until 6 pm, show a relatively greater frequency of female fatalities.

The previously noted concentration of pedestrian fatalities on weekends is shown in Table 2 to be closely associated with the hours from midnight to 6 am. During this six-hour period, 85.2 per cent of all fatal pedestrian accidents are confined to weekend evenings.

There is a consistent relationship between the hour of the day and the likelihood that the pedestrian victim had been drinking shortly before the accident. No alcohol is detected in the bloodstream of any of the 18 fatally-injured pedes-

trians who were struck between 6 am and noon. Of those pedestrians 14 years of age or older who were fatally injured during the afternoon, 7.5 per cent show detectable blood alcohol. This frequency rises to 19.7 per cent among victims struck between 6 pm and midnight and increases dramatically to 83.3 per cent of the fatalities occurring between midnight and 6 am.

Age of victim: Table 3 represents the Rhode Island pedestrian fatality data classified according to the sex and age of the victim. When the numbers of victims are converted to mortality rates per 100,000 population per year, two observations emerge. First, the age-specific pedestrian mortality rates are invariably higher for men than for women. Second, the rate for both sexes is higher for those below age 14 and those older than 65 years of age. When pedestrian fatalities are viewed as risk rates rather than as crude numbers, the most vulnerable group appears to be those Rhode Islanders who are 75 years of age or older. While an overall male : female ratio of 2.4 is observed when age-specific mortality rates are employed, this ratio varies substantially with age. Below the age of five years, for example, the ratio is 1.0 (ie, the number of male victims equals the number of female victims). In contrast, the ratio

Table 1. — Pedestrian Fatalities in Rhode Island: Season of Accident

Season	Males	Females	Total	Per Cent of Accidents		
				Weekend*	Late Night†	Positive Blood Alcohol‡
Winter	32	17	49	49.0	28.6	27.8
Spring	33	10	43	48.8	23.4	33.3
Summer	18	10	28	53.6	28.6	31.6
Autumn	37	16	53	54.7	30.2	35.1
TOTAL	120	53	173	51.4	27.8	31.1

* Friday, Saturday, and Sunday. If pedestrian fatalities were randomly distributed, the percentage should be 42.9 per cent.

† Defined as the interval between 9 pm and 3 am. If pedestrian fatalities were randomly distributed, the percentage should be 25 per cent.

‡ Concentrations at or above 0.06 gm per cent in pedestrian victims aged 14 years and older.

Table 2. — Pedestrian Fatalities in Rhode Island: Hour of Accident

Interval	Males	Females	Total	Sex Ratio	Per Cent of Accidents	
					Weekend*	Positive Blood Alcohol†
0000-0559‡	21	6	27	3.5	85.2	83.3
0600-1159	13	5	18	2.6	33.3	-0-
1200-1759	31	17	48	1.8	50.0	7.5
1800-2359	55	25	80	2.2	45.0	19.7
TOTAL	120	53	173	2.3	51.4	31.1

* Friday, Saturday, and Sunday.

† Concentrations at or above 0.06 gm per cent in pedestrian victims aged 14 years and older

‡ 24-hour clock

Table 3. — Pedestrian Fatalities in Rhode Island: Age of Victim

Sex	Age	Number	Rate per 100,000*	Per Cent of Accidents†			Positive Blood Alcohol‡
				Weekend	Late Night	Winter	
MALE	0-14	27	4.6	48.1	3.7	14.8	0
	15-24	17	3.4	47.1	64.7	29.4	60.0
	25-54	36	3.8	63.9	41.7	27.8	48.5
	55-64	11	3.9	63.6	27.3	27.3	18.2
	65-74	14	7.6	21.4	28.6	28.6	16.7
	75 +	15	12.9	46.7	6.7	46.7	0
TOTAL		120	4.4	50.8	29.2	26.7	33.7‡
FEMALE	0-14	16	2.8	31.3	6.3	18.8	0
	15-24	5	1.0	100.0	40.0	40.0	60.0
	25-54	14	1.4	64.3	64.3	42.9	36.4
	55-64	3	0.9	100.0	0	0	33.3
	65-74	4	1.5	50.0	0	50.0	0
	75 +	11	5.5	36.4	9.1	36.4	9.1
Total		53	1.8	52.8	24.5	32.1	27.3‡

* sex and age-specific mortality rates

† see Table 1 for definitions

‡ percentage of positive blood alcohol = $\frac{\text{number of victims older than 14 years with positive result}}{\text{number of victims older than 14 years analyzed for BAC}}$

of males to females increases to 2.9 for older victims.

The weekend clustering of pedestrian fatalities is more compellingly associated with victims between the ages of 25 and 64 years of age (Table 3). Similarly, the late night concentration of pedestrian fatalities is most readily observed in the male victims between the ages of 15 and 54 years of age. For females in this age category, the late night clustering is even more dramatically demonstrated. In contrast, only one of the 18 female pedestrian fatalities who were 55 years of age or older was involved in an accident during the hours designated as late night.

The percentage of fatal pedestrian accidents taking place during the winter months is slightly greater in those 65 years of age or older, when compared with the mortality rates of younger age categories.

Alcohol: The linkage between positive blood alcohol tests and young adulthood is again seen in Table 3. Of the male and female pedestrian victims in the 15-24 year category, 60 per cent had blood alcohol concentrations equal to or greater than 0.06 gm per cent. In general, the correlation between positive blood alcohol levels and pedestrian fatality is slightly more compelling for males (33.7 per cent) than for females (27.3 per cent).

The incidence of detectable psychoactive drugs was negligible in this series of 173 pedestrian deaths. Barbiturates were detected in three vic-

tims, Δ -9 tetrahydrocannabinol (marijuana) in one, and dilantin in one. The carbon monoxide levels were within the normal range.

Marital status: Table 4 summarizes the marital status of the 173 pedestrian victims. The frequency of those who are single, married, or other (ie, divorced, separated, or widowed) also is analyzed by sex and age category. For purposes of comparison, the age-stratified marital status of the total male and female population of Rhode Island was computed from 1980 US Bureau of the Census tapes. The percentage of those married among the male pedestrian fatalities is invariably lower than in the age-stratified general population of the state. In general, the percentage of single or no longer married victims is greater among the pedestrian fatality population. The one exception to this observation may be found among the female pedestrian fatalities who are 65 years of age or older.

Occupation: There are 108 persons between the ages of 21 and 65 years among these 173 pedestrian fatalities. The following frequencies of occupations were recorded: blue-collar and manual labor, 23.1 per cent; non-professional office or mercantile work, 13.0 per cent; professional or managerial activity, 11.1 per cent; unemployed, 31.5 per cent; unknown or unstated, 21.3 per cent. If the unknown fraction is distributed in the same proportions as the known percentages, the following frequencies are derived:

Table 4. — Pedestrian Fatalities in Rhode Island: Marital Status and Sex

	Age in Years			
	15-24	25-44	45-64	65*
MALES:				
Pedestrian fatalities:				
Single	88.2%	34.6%	14.3%	10.3%
Married	5.9	50.0	61.9	55.2
Other	5.9	15.4	23.8	34.5
Rhode Island population:*				
Single	88.2	18.2	7.4	6.9
Married	10.8	73.0	82.9	71.3
Other	1.0	8.8	9.7	21.8
FEMALES:				
Pedestrian Fatalities:				
Single	80.0	37.5	11.1	13.3
Married	0	37.5	66.7	40.0
Other	20.0	25.0	22.2	46.7
Rhode Island population:*				
Single	79.1	12.6	7.5	12.0
Married	18.4	72.5	71.9	32.6
Other	2.5	14.9	20.6	55.4

* Age-stratified marital status of total Rhode Island population as computed from US Bureau of the Census tapes for 1980.

blue-collar and manual labor, 29.4 per cent; non-professional office or mercantile work, 16.5 per cent; professional or managerial activity, 14.1 per cent; and unemployed, 40.0 per cent.

Discussion

If the probability of a pedestrian fatality is merely a function of the extent to which public roads are used, two corollaries would be expected. First, the greatest number of fatal traffic accidents should occur when both pedestrian and vehicular traffic are at their most intense. Second, those persons in the age ranges which frequently use the roads should exhibit the highest pedestrian mortality rates. In fact, neither of these generalities prevail. The highest concentration of pedestrian deaths occurs after dark when vehicular and pedestrian traffic is low. Moreover, the pedestrian mortality rates are lowest among the very age groups which are the most exposed to moving vehicular traffic.

If pedestrian fatalities are not randomly distributed in proportion to roadway usage, the data collected in this study suggest the following generalizations concerning the selective risks of pedestrian fatalities.

First, males of all ages are more likely to be the pedestrian victims of traffic accidents. The overall male: female ratio of 2.4 noted in the Rhode Island data is confirmed by other epidemiologic surveys of pedestrian fatalities.⁵⁻⁸ A more valid measure of vulnerability, however, is found in

mortality rates calculated per 100,000 population. When such statistics are used, the male preponderance is evident in all age ranges, but least apparent for males aged 14 years and younger or 75 years and older.

The following characteristics describe the typical adult male pedestrian victim in Rhode Island. He is in his 40s, unmarried or separated, and is unemployed or performs manual labor. More often than not, he is intoxicated at the time of the accident, especially if the fatal impact occurs during the evening hours. This profile is similar to the one assembled by Haddan and his colleagues.⁸ These investigators noted that pedestrian fatalities, when compared to a control group, tended to be single or no longer married, foreign born, and of lower socio-economic status.

Second, the seasonal pedestrian mortality rate is correlated with the number of hours of darkness per day, highest in winter and lowest in summer, despite the obvious fact that pedestrians are less mobile in cold and dark intervals. Almost 62 per cent of the pedestrian deaths were recorded between 6 pm and 6 am, with the majority occurring between 9 pm and midnight.

Third, except in late night pedestrian deaths, alcohol consumption is not a common association. About five of every six fatalities between midnight and 6 am have blood alcohol concentrations exceeding the physiologic threshold of 0.06 gm per cent. The association with alcohol is most apparent in victims between 15 and 24 years of

age where positive blood alcohol concentrations are seen in 60 per cent of the victims regardless of sex.

The accidents involving elderly pedestrians are more difficult to characterize or explain. Certainly, the elderly are at greater general risk. An 80-year-old male, for example, faces a four-fold enhanced risk in comparison with a 20-year-old. For females, this relative risk becomes five-fold.

Some cautious generalities, however, may be made regarding pedestrian fatalities among the elderly. The fatal accident occurs more commonly in winter weather, especially when visibility is diminished. While alcohol usage is not a factor in the unique vulnerability of these elderly victims, it undoubtedly plays a significant role for the drivers of the vehicle involved in the fatal accident. Some impairment of pedestrian judgment is the likely basis of many of these tragic accidents.¹⁻³ Distraction or overt confusion may deprive the older person of the intense concentration needed to cross roads with safety. A slower pace may increase the time spent in traffic lanes. Impaired vision and hearing, both more common in the elderly, may also serve to increase the probability of pedestrian accident. Flawed judgment resulting from an underlying organic dementia also probably contributes to the problem.¹⁰

Does prior organic illness predispose the pedestrian to traffic accidents? In the case of drivers, for example, Waller has found that those suffering from diabetes, alcoholism, or mental illness averaged "twice as many accidents per 1,000,000 miles of driving" as drivers in an age-adjusted comparison cohort.⁹ No mention is made of augmented rates of organic disease in fatally-injured pedestrians, but the likelihood exists. The role of suicidal intent, clearly a factor in some pedestrian deaths, is very difficult to measure.

The present data provide a limited explanation for the traffic fatalities involving young or middle-aged, unmarried adult pedestrians, a population more likely to be on the public roads during the hours of darkness, either as drivers or pedes-

trians. While there is an intuitively obvious association between diminished visibility, fatigue, and altered judgment induced by alcohol affecting both driver and pedestrian, this correlation is only an inference rather than a verified casual relationship that is derived from epidemiological surveys such as this one.

No comparable explanations are available for child victims. There is some anecdotal information suggesting a greater frequency of physical impairment, obesity, and emotional travail among this group. Similarly, we cannot explain the high risk of pedestrian fatality among the elderly other than by invoking the spectre of frailty, cognitive impairment, and confusion. There is as yet no pathologically-based evidence, however, that Alzheimer's disease is more common among the elderly fatalities when compared with age-matched controls, although there is every likelihood that this may be the case. Further inquiry must be directed to a specific study of the backgrounds and medical conditions of the child and elderly victims to clarify the reasons for their selective vulnerability.

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SPECIAL REPORT

The Rhode Island Board of Medical Review

A. A. Savastano, MD

Established in 1976 under Chapter 5-37-1 of the General Laws of Rhode Island, the Board of Medical Review is empowered to investigate, review, and monitor the professional conduct of physicians and to impose sanctions or other conditions on those found guilty of unprofessional activities.

The Board consists of nine members appointed by the governor for not more than two consecutive, three-year terms of office: five physicians, one hospital administrator; one public member; one attorney to serve as a public member; and in an ex-officio capacity, the Director of the Rhode Island Department of Health. After completing two terms, a member may be eligible for reappointment after a one year hiatus. The daily operations of the Board are carried out by an Executive Director assisted by legal counsel and a staff which includes investigators, stenographers, and secretaries.

The activities of the Board are financed through an annual fee levied on all licensed physicians. Hospitals must also pay an assessment which is based on their bed capacity. Each physician who holds an active Rhode Island medical license, whether or not practicing in the state, must pay the annual charge. Physicians may be exempted from fees and assessments by having

their names placed on a list of inactive physicians at the Division of Professional Regulation. The Board is not authorized either to place physicians on this list or to grant exemptions from the annual assessment. While on inactive status, physicians may not perform any medical services either for themselves or for their families or write prescriptions. This prevails whether or not payment is received.

Powers and Duties of the Board

The Board is empowered to investigate all allegations of unprofessional conduct on the part of physicians. In addition to direct complaints from patients, it receives reports of disciplinary actions by hospitals; reports of civil or criminal proceedings in which physicians are found guilty of malpractice or any other civil or criminal malfeasance; reports from insurance carriers of compromises, settlements, or verdicts in medical malpractice cases; and other sources.

Unless it can be proven that the complaint was filed with malicious intent, Rhode Island statute grants immunity from any action for defamation of character to persons who register complaints against physicians. The Board itself is similarly exempted from such actions unless malice is clearly demonstrated during the investigation or hearing proceedings.

Procedure

Except when public hearings are required by statute, all proceedings before the Board of Medical Review generally are confidential. The procedure followed for handling cases is outlined below.

Upon receipt of a written complaint or other information, an investigation of unprofessional conduct is initiated. The physician is asked to respond in writing to the written complaint or to the information which the Board has received. After the written response is received, the matter

Based on a paper presented at a conference sponsored by the RI Division of Drug Control, "The Prevention of Prescription Drug Misuse, Abuse, and Diversion," April 11, 1984, Providence, Rhode Island.

A. A. Savastano, MD, is in the private practice of orthopedic surgery in Providence, Rhode Island; Surgeon-in-Chief Emeritus, Division of Orthopaedic Surgery, Rhode Island Hospital; and Clinical Professor of Orthopaedic Surgery, Brown University Program in Medicine. He currently serves as Chairman of the Board of Medical Review.

Table 1. — Prior Docketed Inquiries
Pending as of December 31, 1981

ALLEGATION	DISPOSITION — 1982		
Unprofessional conduct	8	Pending	5
JUA/malpractice reports	8	Dismissed	8
Improper prescribing	9	Dismissed	8
Hospital reports	3	Pending	9
Fees	1	Pending	3
Records	1	RIMS	1
Acupuncture	2	Resolved by parties	1
Overutilization	6	Dismissed	2
Physician impairment	3	Suspended	1
		Pending	3
	41		41

is assigned to a subcommittee charged with performing a preliminary investigation. The Board may issue subpoenas on its own authority to compel the production of documents or other written records or to summon witnesses and defendants for investigations and hearings. If the summoned person willfully ignores a subpoena or refuses to answer appropriate questions during the proceedings, the Board may seek a contempt citation from the Superior Court.

If the preliminary findings substantiate the allegations of misconduct, a hearing committee is appointed, the specification of charges prepared, and a formal hearing scheduled. Verbatim transcripts must be prepared of all hearings from either a tape recording or stenographic records. After reviewing a transcript of the proceedings, the hearing committee prepares a report for consideration by the full Board. A copy of the report also is sent to the physician. Should there be a finding of unprofessional conduct, the physician is informed that the report will be presented to the Board at its next meeting. The Board, if it concurs with the findings of misconduct, must reconvene for the purpose of imposing sanctions upon the defendant.

Board Sanctions

The following sanctions are available to the Board: an oral reprimand at the hearing; suspension, limitation, or restriction of a license to practice medicine for up to five years; revocation of a medical license for an indefinite period; mandatory care, counseling, or treatment of the defendant by a physician acceptable to the Board; mandatory participation in a program of continuing medical education; or a requirement that the defendant practice medicine only under the direction of a physician acceptable to the Board for a specified time period. The defendant also may be

Table 2. — Docketed Inquiries as of June 30, 1982

ALLEGATION — 1982	DISPOSITION — 1982		
Unprofessional conduct	15	Pending	9
JUA/malpractice reports	16	Dismissed	11
Insurance company reports	24	No jurisdiction	29
Improper prescribing	5	Pending	5
Hospital reports	2	Pending	2
Fees	4	RIMS/RISOPS	4
Records	1	Resolved by parties	1
Unpaid assessments	5	Suspended	1
Unlicensed practice of medicine	1	Reinstated by Attorney General	1
	73		73

assessed up to \$2,500 for the administrative costs of the Board proceedings.

The right to judicial review of Board decisions is available to physicians whose medical licenses have been suspended or revoked or who are otherwise aggrieved by a Board action. The appeal must be initiated within ten days of the Board's decision by sending a notice of appeal to the Board Secretary and by following the civil procedure established by the Superior Court.

Board Meetings

The Board holds open public meetings, unless otherwise scheduled, on the third Wednesday of each month at its offices at 100 India Street, Providence, Rhode Island. Committee meetings are scheduled as frequently as necessary. These meetings are confidential, except when statutory requirements for open meetings prevail.

Board Actions

During the period 1977 through 1981, a total of 562 inquiries were docketed. Of these, 407 have been closed, with 64 additional closed matters awaiting ratification and 91 cases pending.

The disciplinary actions against physicians during this period include: license revoked-4, license suspended-3, license surrendered-3, and probation-2. The following procedural actions were taken: license suspended for nonpayment of assessments-19, license reinstated after payment-11, and license surrendered because of illness-2. In six cases, the matter became moot after the physician died. As of January 1, 1982, there were 1,989 physicians holding active Rhode Island medical licenses.

Unprofessional Conduct

The following activities constitute unprofessional conduct: the fraudulent or deceptive procuring

or use of a medical license; all advertising of medical business which is intended or has a tendency to deceive the public; conviction of a crime involving moral turpitude; conviction of a felony or of a crime arising from the practice of medicine; abandonment of a patient; addiction to narcotics; habitual intoxication or rendering professional services to a patient while under the influence of either drugs or alcohol; promotion of drugs, devices, appliances, or other goods and services for the purpose of exploiting the patient for financial gain; immoral conduct by a physician in the practice of medicine; willfully making and filing false reports or records in the practice of medicine; and the gross, willful, and continued overcharging for professional services, including filing false statements to collect fees for services which have not been performed.

The prior docketed inquiries pending as of December 31, 1982, and the docketed inquiries as of June 30, 1982 are shown in Tables 1 and 2.

Diversion and Abuse of Prescription Drugs

It has been estimated that seven million Americans annually use barbiturates, tranquilizers, amphetamines, narcotics, and other prescription drugs for nonmedical purposes, frequently with disastrous results. Eight of the leading ten drugs reported by medical examiners as the primary cause of death are prescription agents. There currently are approximately 500,000 registered pharmacies and other private enterprises which annually dispense an estimated 20,000 different brandname products. This annual volume includes approximately 185,000 pounds of opium derivatives, 45,000 pounds of synthetic narcotics, and 4,172 pounds of amphetamines. Among the drugs frequently abused are barbiturates, benzodiazepines, and phenothiazines. Combinations with alcohol or with other sedative hypnotics may cause respiratory problems or death. Other offenders include Methaqualone®, Talwin®, and

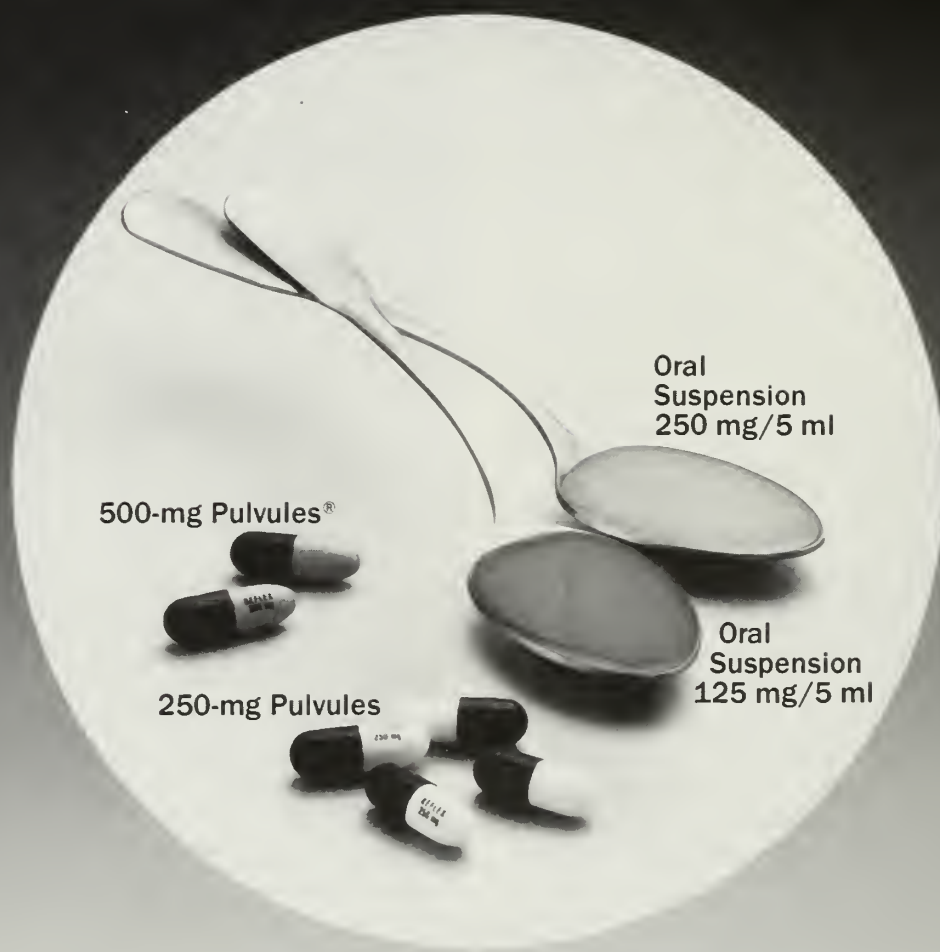
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In addition to misuse of prescribed medications, the substance abuse problem poses a major public health threat, involving some ten million alcoholics, two million non-narcotic drug abusers, and 500,000 heroin addicts. It is unfortunate that some physicians are included among the victims of substance abuse. Some have suggested that they may be especially vulnerable to this problem because of occupational pressures and the availability of drugs. There often is a high incidence of family problems, depression, and underlying psychopathology for many of these cases. Such resources as the Impaired Physicians Committee of the Rhode Island Medical Society have proven to be invaluable in restoring these physicians to health and satisfying professional careers.

We also must consider the problems presented by "dated, drug treatment, and script" doctors. "Dated" physicians require additional consultation and training to improve their prescribing practices. If educational efforts fail, restrictions must be placed on their licenses to protect the welfare of patients. The "drug treatment" doctor, if practicing responsible medicine, should be left alone to address the difficult problem of addictive disease for the benefit of both the individual and society. The "script" doctor must be prosecuted vigorously as is any other criminal.

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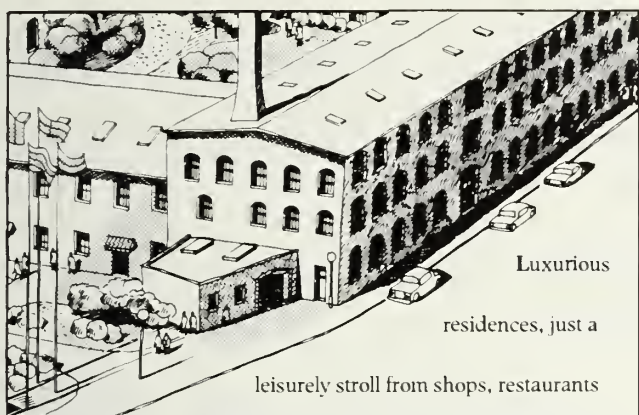
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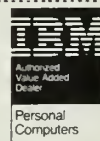
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Short-Course Antibiotic Prophylaxis in First-Trimester Abortion

Complications Were Acceptably Low and Consistent with Previous Studies

John DiOrio, MD

Numerous changes have occurred in the administration of prophylactic antibiotics since significant research by Burke in the 1960s showed that a critical period exists in the treatment of staphylococcal infection in guinea pigs under experimental conditions.¹ Within the field of obstetrics and gynecology, the time span necessary for prophylaxis has been reduced from several days to less than 24 hours for hysterectomies and primary cesarean sections. In the case of elective termination of pregnancy, however, many centers still follow a three- to five-day prophylactic protocol. The purpose of the following study was to determine the safety and efficacy of a short (six-hour) perioperative course of antibiotics in elective first-trimester abortion procedures.

Methodology

From October 1982 through January 1983, 478 patients underwent first-trimester suction termination of pregnancy at a local outpatient ambulatory-care facility. The procedures were performed by board certified obstetrician-gynecologists utilizing the standard technique. All patients received a paracervical block using

From the Department of Obstetrics and Gynecology, Women & Infants Hospital, and the Brown University Program in Medicine

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15-20 ml of one per cent Xylocaine® after a Betadine® vaginal preparation was performed. The study group (A) received 500 mg tetracycline by mouth at the time of the procedure and 500 mg six hours later (total dose 1 g). The standard therapy group (B) received 250 mg tetracycline orally at the onset of the procedure and 250 mg every six hours for four days (total dose 4 g). Gonorrhea cultures were obtained in all cases.

The patients were followed up either by examination from their physicians in two to three weeks or by telephone calls from staff members. Infection was defined as: (1) fever of 100°F of pelvic origin, developing after the procedure and lasting for more than 24 hours; (2) a pelvic examination exhibiting findings of uterine and parametrial tenderness; or (3) a diagnosis of pelvic infection by the referring physician.

Results

Of the total 478 patients studied, there were 236 in the study group (A) and 242 in the standard therapy group (B). The two groups consisted of predominantly white middle-class women, with the majority having completed a high-school education. The study group and the control subjects were similar in age (average 23-24 years old), gravidity, parity, previous abortions, and prior history of pelvic inflammatory disease. The average gestational age at the time of the procedure in both groups was between eight and nine weeks. In group A, 115 patients (48.7 per cent) were examined between two and three weeks after the procedure and 121 (51.3 per cent) were telephoned. In group B, 148 (61.2 per cent) received an examination and 94 (38.8 per cent) had telephone follow-up.

There were only three complications as a result of infection. The study group yielded two patients with infection. One required oral antibiotics for ten days, and the other underwent an outpatient dilatation and curettage and received ten days of antibiotic therapy for suspected endomyometritis. The one patient in the control group who required treatment received oral antibiotics for ten days. No hospitalizations occurred in either group.

The rate of infection in the study group was 1.7 per cent if only those patients examined by our staff are included, and 0.8 per cent if all patients are considered. For the control group, the rates were 0.7 and 0.4 per cent respectively. Although the rate of infection in group A is slightly higher than that in group B, the differences are not statistically significant.

Discussion

In 1974 and 1975, Hodgson and her colleagues reported on their findings with patients who had undergone first-trimester abortion procedures. It was shown that complication rates were acceptably low and that problems resulting from infection were reduced, when compared to placebo, by the prophylactic use of antibiotics.^{2,3} In those studies, patients received 1.5 g oral tetracycline two to three hours before the procedure and 500 mg by mouth every six hours for four days.

In a more recent study, Soone-Holm et al showed that the administration of antibiotics reduces the incidence of post-abortion infection during the first trimester only in those patients with a previous history of pelvic inflammatory disease.⁴ In that study, two million units of penicillin G were given intramuscularly 30 minutes before and three hours after the procedure, followed by 350 mg pivampicillin three times daily for four days.

In the current study, only the antibiotic dosage and duration of therapy were selected as variables. It was found that a short perioperative course of antibiotics (tetracycline 1g total, completed within six hours) produced results equivalent to the conventional usual four-day course (total dose 4 g). Complications due to infection were acceptably low in each group and consistent with previous studies on the subject.⁵

These results are not surprising as similar trends are observed in other phases of obstetrics and gynecology where shorter courses of prophylaxis are found to be as effective as longer measures. In the case of primary cesarean section and for vaginal and abdominal hysterectomy, it is common to terminate prophylaxis within 12-16 hours.^{6,8}

It is concluded that the shorter course of antibiotic prophylaxis in elective termination of pregnancy is safe and cost-effective and that the common practice of three-to-five day prophylaxis should be abandoned. In view of the short operating time and low general incidence of infection noted with mid-trimester dilation and evacuation, it is probable that a short course of antibiotic prophylaxis also would be acceptable for this group.

Summary

In the fields of obstetrics and gynecology, the time period for antibiotic prophylaxis has been reduced to less than 24 hours for such major procedures as hysterectomy and primary cesarean section. This study compared the use of short-course antibiotic prophylaxis with the conventional three-to-five day therapy for elective first trimester abortion. No significant difference in efficacy was found.

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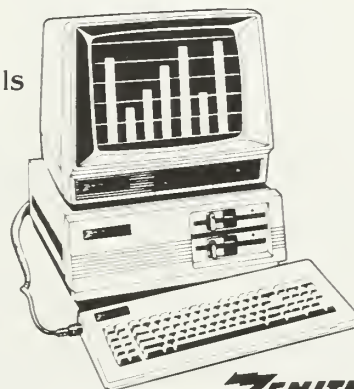
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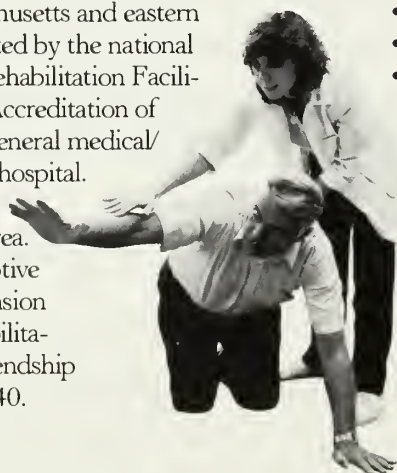
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The Impact of Advanced Life Support Training for Nursing Personnel in an Outpatient Renal Dialysis Center

Such Training Significantly Improves the Chances of Survival

Joseph A. Chazan, MD
Lucille Pono, RN
Kenneth B. Linhares

Since the reintroduction of closed chest resuscitation in 1960 and the subsequent refinement of these techniques, the survival of patients experiencing sudden cardiac arrest has improved significantly. More recently, the prompt application of advanced cardiac life support, including cardiac drugs, defibrillation, and insertion of an esophageal or endotracheal obturator airway, has increased the number of successful resuscitations.

We reviewed the results of treatment administered to patients who suffered sudden cardiac arrest between 1973 and 1982 at the Artificial Kidney Center of Rhode Island, a free-standing outpatient dialysis facility in East Providence, Rhode Island. All nurses at the Center must be certified in basic life support. In 1981, selected nursing personnel also were trained to provide advanced cardiac life support.

Methods

Center personnel have performed more than 200,000 treatments on 600 different patients during the past 10 years. Approximately 650

treatments per week currently are provided to an average of 250 patients. We reviewed our experience with all patients who suffered sudden cardiac arrest during dialysis therapy at the facility. Between 1973 and 1980, 12 patients, none of whom were successfully resuscitated, suffered sudden cardiac arrest. In 1981 and 1982, after selected nurses received training in advance cardiac life support, 16 patients suffered cardiac arrest. Of these, six were admitted to the hospital and four recovered completely.

Treatment of acute cardiopulmonary arrest is instituted immediately by nursing personnel. After therapy has been initiated, the East Providence Rescue Squad is called. The rescue unit usually arrives within minutes, and telemetry is provided to the Coronary Care Unit at Rhode Island Hospital. If a physician is present at the Center, he supervises the treatment of the arrest. In the absence of a physician, treatment is supervised by nursing personnel, and the patients are transferred to the Rhode Island Hospital after they have been stabilized.

Results

Table 1 shows the results of treatment of all patients who suffered acute cardiopulmonary arrest between 1973 and 1982. When the age of these patients is compared to that of the general population, it is apparent that they were older and that many had preexisting coronary artery disease, previous myocardial infarction, and evidence of ventricular irritability. All of the patients who suffered acute cardiopulmonary arrest between 1973 and 1980 died in the emergency room at the Rhode Island Hospital where they had been transported (Table 1). Except for two patients, all were in ventricular fibrillation. Since

Joseph A. Chazan, MD, Medical Director, Artificial Kidney Center of Rhode Island, East Providence, Rhode Island; and Clinical Associate Professor of Medicine, Brown University Program in Medicine.

Lucille Pono, RN, Nursing Administrator, Artificial Kidney Center of Rhode Island, East Providence, Rhode Island.

Kenneth B. Linhares, Emergency Cardiac Care Coordinator, American Heart Association, Rhode Island Affiliate, Pawtucket, Rhode Island.

Table 1. — Comparison of Patients with Cardiopulmonary Arrest and Other Dialysis Patients

Number	Cardiopulmonary Arrest			Dialysis Population		
	Sex	Age range	Average age	Sex	Age range	Average age
16	M	56-87	68	M	16-82	54
12	F	60-73	78	F	18-80	54

Table 2. — Patients with Cardiopulmonary Arrest

	Number	Age Range	Average Age	Ventricular Fibrillation	Admitted to Hospital	Discharged from Hospital
1973-1980	12	58-78	68	10	0	0
1981-1982	16	60-87	73	13	6	4

1981, six of 16 patients who suffered cardiopulmonary arrest were successfully resuscitated and admitted to the hospital. Two of these patients subsequently died of pulmonary infection, although their cardiac status had been returned to normal. Four patients were successfully resuscitated without sequelae and were discharged after an uneventful hospitalization. Two of these patients subsequently suffered another myocardial infarction and died.

Discussion

Our initial experience revealed that the number of patients suffering acute cardiac arrest at the Artificial Kidney Center of Rhode Island was low, related in part to the younger age of the treated population and the association of fewer serious medical illnesses. More recently, however, the dialysis population has become older. More of these patients have multiple serious medical problems in addition to their chronic renal failure. This may, in part, explain why while there were only three pulmonary arrests from 1973-1976, there were nine from 1977-1980 and 16 in 1981 and 1982. All of the patients suffering cardiopulmonary arrest died until Center nurses were trained in advanced cardiac life support and were available for resuscitation. After such training was instituted, six patients were successfully resuscitated, and four were discharged from the hospital without sequelae. This dramatic change in the success rate seems to indicate that advanced cardiac life support training is extremely effective for the nurses who provide direct patient care. All free-standing dialysis centers should have

enough trained nurses to provide advanced cardiopulmonary life support. Other outpatient facilities should also consider similar training programs for their nursing personnel.

Summary

Patients suffering from sudden acute cardiac arrest at the Artificial Kidney Center of Rhode Island during a ten-year period were reviewed. During the first eight years, all patients experiencing acute cardiac arrest died despite prompt attention by nurses and physicians. During the past two years, after nursing personnel were trained in advanced cardiac life support, 25 per cent of the patients suffering acute cardiac arrest were successfully resuscitated and discharged from the hospital after admission.

It is concluded that training of nursing personnel greatly improves the chances for survival for these patients suffering acute cardiac arrest.

Acknowledgments

We are grateful to the Rhode Island Heart Association for training nurses who work at the Artificial Kidney Center of Rhode Island in advanced cardiopulmonary life support, to the East Providence Rescue Squad, and to the personnel at the Coronary Care Unit, of the Rhode Island Hospital. In addition, we are most grateful to the nursing personnel at the Artificial Kidney Center of Rhode Island who provided the treatment for these patients.

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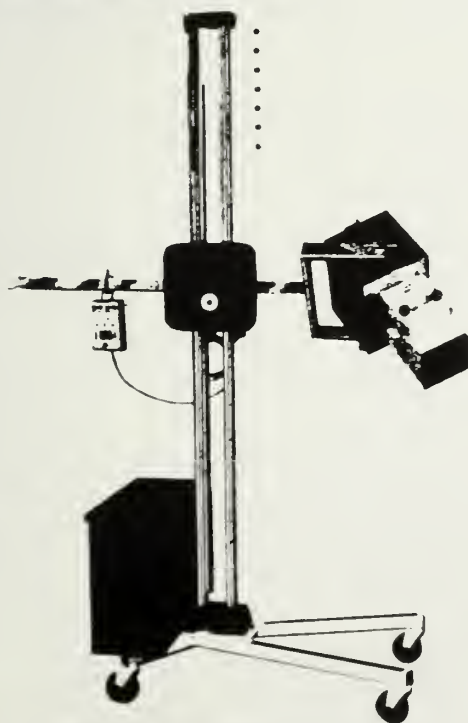
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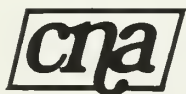
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The Rhode Island Medical Society Committee on Impaired Physicians, chaired by Dr Herbert Rakatansky, meets monthly. It is a standing committee of the Society charged with "helping physicians whose professional judgments and capabilities are impaired by their difficulties with chemical dependency or other illnesses."

The Committee handles inquiries in *complete confidence*. If you know of a physician who needs an advocate and support in obtaining necessary treatment, please call or write Dr Rakatansky c/o The Committee on Impaired Physicians, Rhode Island Medical Society, 106 Francis Street, Providence 02903 (401/331-3207).

cessfully. When presented with an outline map of the United States, he recognized it as such and could point to the location of major cities presented verbally. Although he copied complex geometric figures poorly, he was able to draw a diagram of the floor plan of his house and of his garden which, according to his wife, was quite

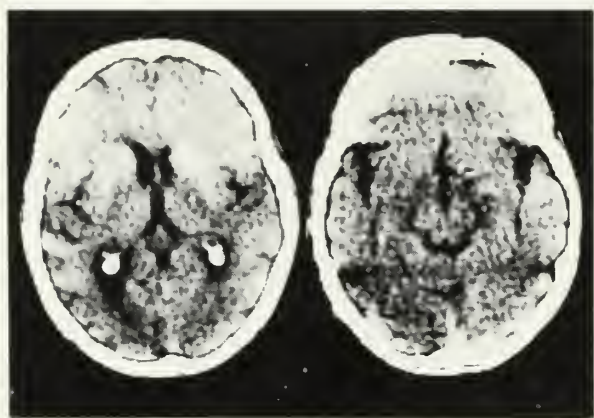


Fig 1. X-ray computed tomographic scan performed two years after onset of illness demonstrates mild atrophy of the left temporal lobe and significant dilatation of the left lateral ventricle.

accurate. When presented with photographs of popular personalities, he could not identify them by name, but could demonstrate recognition by describing their salient personal characteristics. His visual and spatial memory were intact, and he was aware of many current events. A general physical examination was normal, and neurological examination revealed slowing and irregularity of rapid alternating movements performed with the right hand.

Over the next three months his right arm became progressively clumsier, and he lost the ability to use a telephone effectively. He could still follow most commands and insisted that he understood what others said. Quick irregular muscle jerks in his right arm appeared for the first time. A repeat EEG was abnormal because of shifting theta and delta slowing and sharp waves which appeared bilaterally over the frontal and temporal regions, although more so on the left side. The lumbar spinal opening pressure was 180 mm of cerebrospinal fluid, which contained 58 per cent mg protein and no cells.

Non-invasive studies of the carotid circulation were normal. Tests of cerebral blood flow and oxygen utilization demonstrated reduced values over both hemispheres without asymmetries. The Wechsler Adult Intelligence Scale yielded a full-scale score of 90 without significant discrep-

ancies between the aggregate verbal and performance scores. Some variations, however, were observed among the WAIS subtests, especially in the verbal scale. Mental calculations, such as serial sevens, were performed poorly, and his digit span was three forward and two backward. He scored in the defective range on the Wechsler Memory Scale and performed poorly on the Bender-Gestalt, Ravens Matrices, and Benton Visual Retention Tests. There was no apparent visual agnosia.

Although he frequently seemed appropriately despondent over his progressive deficits during the first two years of his illness, his depression gradually lessened and he often seemed inappropriately jocular. His wood-working and gardening skills declined, and he was forced to stop driving because of his increasingly erratic performance. Coordination of his right arm deteriorated as a result of myoclonus. He was vir-



Fig 2. Left lateral view of the brain showing moderate to severe generalized atrophy, accentuated in the temporal lobe (long arrow) and frontal operculum (short arrow).

tually unable to communicate through speech or gestures and auditory comprehension was also impaired. Although he displayed some dexterity, could walk tandem, and exhibited normal muscular tone and down-going toes, he had lost all self-help skills due to apparent apraxia. During the third and fourth years of his illness, myoclonus worsened and spread to all four extremities, while his gait and balance were relatively preserved. He developed a prominent blepharospasm and bilateral grasping. Bowel and bladder function were retained. Tests of thyroid, liver, renal, and bone marrow function remained normal throughout the illness.

When examined by one of us (SP) four years after onset of the illness, the patient, who was

then 59 years old, appeared alert with fluent speech that was completely incoherent. He responded to his name and apparently recognized his wife, but not his sister. He could not properly hold or use a pencil. Snout and suck reflexes were present; he bit the tongue depressor and would not release it. There was generalized myoclonus made worse with intention; deep tendon reflexes were uniformly brisk, and plantars remained flexor. He demonstrated an abnormal gait by walking bent slightly forward and shuffling his feet along the floor, but retained his balance. During the last two years of his life, he developed generalized seizures, which were controlled with appropriate medication, and deteriorated at a more rapid pace. He declined gradually to a vegetative state and died at age 62 of aspiration pneumonia, six years after the onset of his illness.

Neuropathologic Findings

The brain weighed 1108 g. The gross examination after formaldehyde fixation revealed thin, delicate leptomeninges over the cerebral convexities and at the base of the brain. There was no atherosclerosis of the major cerebral vessels. The convolutions of the cerebral hemispheres were moderately to markedly atrophic throughout the brain, especially the temporal poles, and more so on the left side (Fig 2). The left frontal operculum also appeared atrophic or underdeveloped. Coronal sections confirmed more atrophy on the left side and a significantly larger left lateral ventricle (Fig 3). In the most significantly atrophied areas, the cortical mantle was abnormally thin. No abnormalities of basal ganglia, diencephalon, brain stem, or cerebellum were noted during the gross examination.

Paraffin embedded coronal whole brain sections at the level of the amygdala (Fig 3a) and pineal body (Fig 3b) and numerous smaller sections were stained for cells (hematoxylin-eosin, cresyl violet), myelin (Weil and luxol), glial (Holzer) and neurofibrils (Bielschowsky).

There was widespread nerve cell loss and reactive gliosis in the temporal and parietal lobes, especially in supragranular cortical layers II and III. Neuronal loss and gliosis were less apparent in the frontal and occipital lobes, and not evident in the hippocampus and subiculum.

Neuritic plaques and neurofibrillary tangles (Fig 4) were prevalent and their density of distribution generally corresponded to the degree of neuronal loss and gliosis. In the hippocampus and parahippocampal formation, neuritic plaques were found almost exclusively in area

CA1 and adjacent to the rhinal fissure. Neurofibrillary tangles and granulovacuolar changes were observed also in hippocampal pyramids. Nerve cell loss, gliosis, and neurofibrillary tangles were also apparent in the nucleus basalis of Mynert. The cytoplasm of many cortical pyramids and the large neurons of nucleus basalis were often distended with granular yellow pigment compatible with lipofuscin. Ballooned neurons with pale cytoplasm ("Pick cells") and argentophilic intracytoplasmic inclusions ("Pick bodies") were not identified. Neuritic plaques were also densely distributed in the amygdaloid nuclei and neurofibrillary tangles were prevalent in large neurons of the amygdala and ventrolateral hypothalamus. In contrast to these findings, the cytological appearance of the basal ganglia, thalamus, brainstem, and cerebellum was normal. The white matter of the temporal lobes was reduced in volume and abnormally pale in myelin stains (Fig 3), especially adjacent to neocortical areas which exhibited the most severe

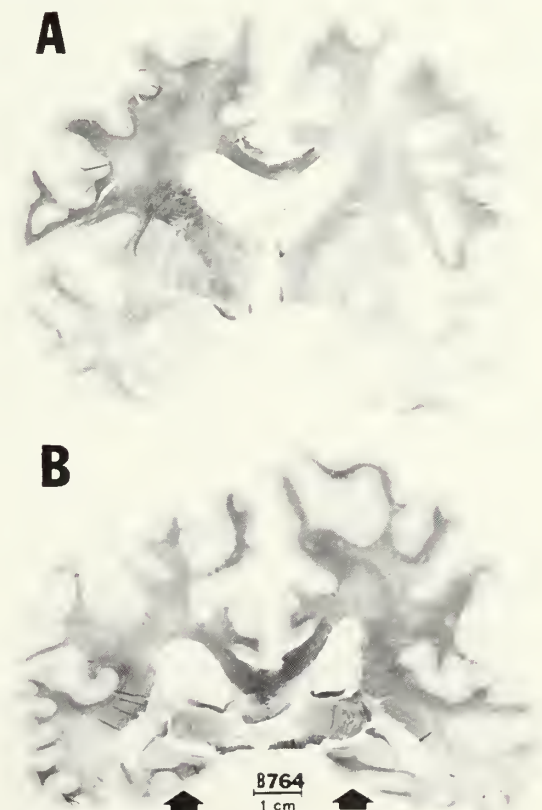
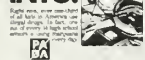


Fig 3. Coronal sections through the amygdala (A) and pineal body (B) showing atrophy of the cerebral hemispheres and enlargement of the lateral ventricles. The atrophic process is more pronounced on the left. The pallor of the white matter under the temporal neocortex with relative sparing adjacent to the parahippocampal gyri is also apparent (arrows) (Weil's stain for myelin).

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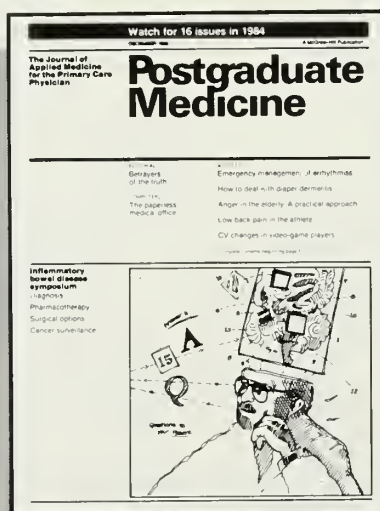
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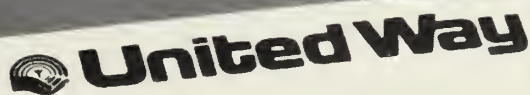
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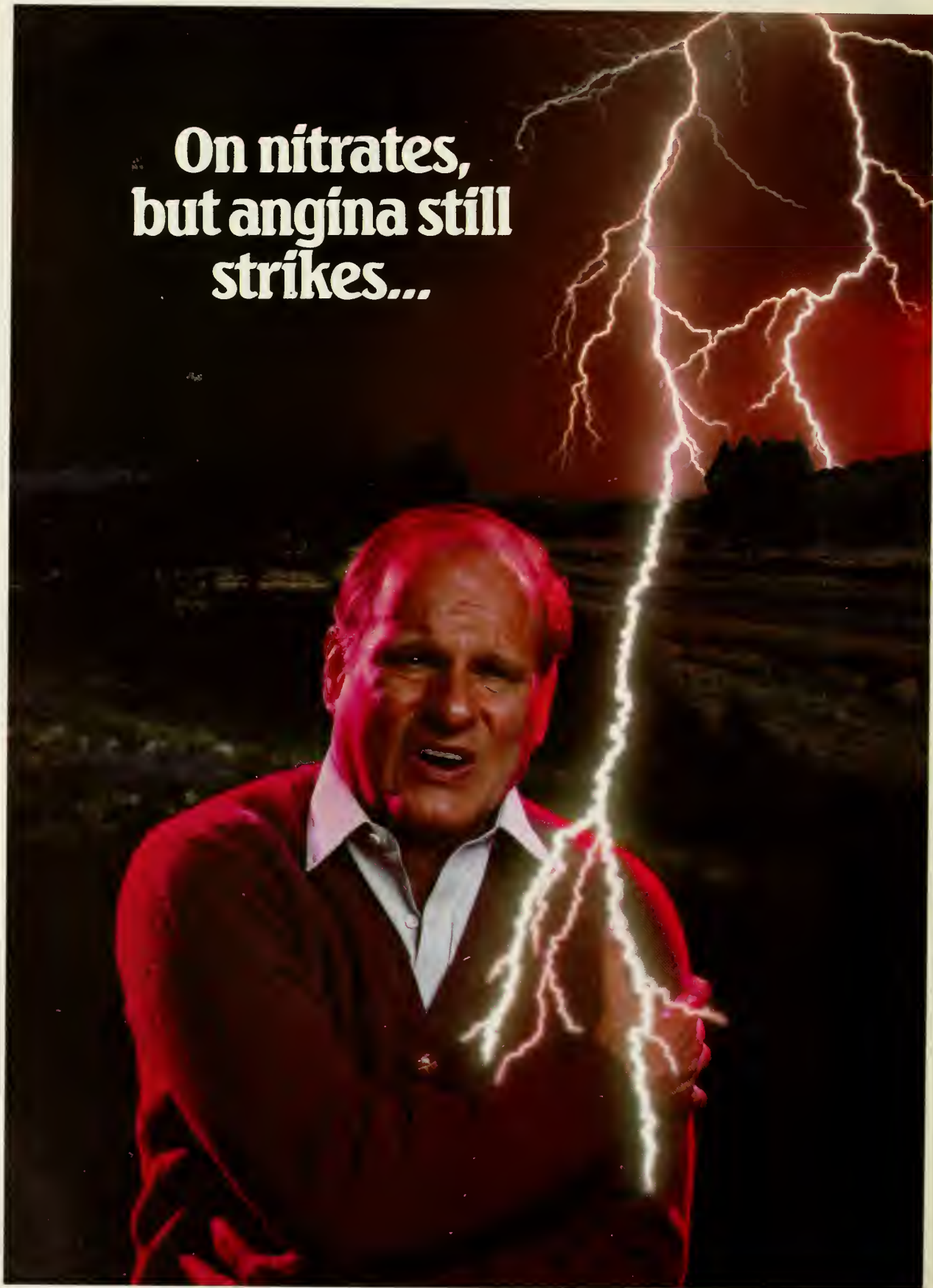
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Cardiovascular contraindications to the use of Isoptin are similar to those of beta blockers: severe left ventricular dysfunction, hypotension (systolic pressure <90 mm Hg) or cardiogenic shock, sick sinus syndrome (if no artificial pacemaker is present) and second- or third-degree AV block.

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Contraindications: Severe left ventricular dysfunction (see *Warnings*), hypotension (systolic pressure <90 mm Hg) or cardiogenic shock, sick sinus syndrome (if no pacemaker is present), 2nd- or 3rd-degree AV block. **Warnings:** ISOPTIN should be avoided in patients with severe left ventricular dysfunction (e.g., ejection fraction <30%) or moderate to severe symptoms of cardiac failure. Control milder heart failure with optimum digitalization and/or diuretics before ISOPTIN is used. ISOPTIN may occasionally produce hypotension (usually asymptomatic, orthostatic, mild, and controlled by decrease in ISOPTIN dose). Occasional elevations of liver enzymes have been reported, patients receiving ISOPTIN should have liver enzymes monitored periodically. Patients with atrial flutter/fibrillation and an accessory AV pathway (e.g., W-P-W or L-G-L syndromes) may develop a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion. AV block may occur (3rd degree, 0.8%). Development of marked 1st-degree block or progression to 2nd- or 3rd-degree block requires reduction in dosage or, rarely, discontinuation and institution of appropriate therapy. Sinus bradycardia, 2nd-degree AV block, sinus arrest, pulmonary edema, and/or severe hypotension were seen in some critically ill patients with hypertrophic cardiomyopathy who were treated with ISOPTIN.

Precautions: ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of overdosage. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, patients should be monitored closely. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function or in patients who have also recently received methyldopa. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patient carefully monitored. ISOPTIN may have an additive hypotensive effect in patients receiving blood-pressure-lowering agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. **Pregnancy Category C:** There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor, and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use.

Adverse Reactions: Hypotension (2.9%), peripheral edema (1.7%), AV block 3rd degree (0.8%), bradycardia: HR<50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%). The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: confusion, paresthesia, insomnia, somnolence, equilibrium disorders, blurred vision, syncope, muscle cramps, shakiness, claudication, hair loss, maculae, and spotty menstruation. Overall continuation rate of 94.5% in 1,166 patients.

How Supplied: ISOPTIN (verapamil HCl) is supplied in 80 mg and 120 mg sugar-coated tablets. July 1982 2068



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Warnings: Peptic ulceration and GI bleeding, sometimes severe, have been reported. Ulceration, perforation and bleeding may end fatally. An association has not been established. Use Motrin Tablets under close supervision in patients with a history of upper gastrointestinal tract disease, after consulting ADVERSE REACTIONS. In patients with active peptic ulcer and active rheumatoid arthritis, try nonulcerogenic drugs, such as gold. If Motrin Tablets are used, observe the patient closely for signs of ulcer perforation or GI bleeding.

Chronic studies in rats and monkeys have shown mild renal toxicity with papillary edema and necrosis. Renal papillary necrosis has rarely been shown in humans treated with Motrin Tablets.

Precautions: Blurred and/or diminished vision, scotomata, and/or changes in color vision have been reported. If these develop, discontinue Motrin Tablets and the patient should have an ophthalmologic examination, including central visual fields and color vision testing.

Fluid retention and edema have been associated with Motrin Tablets; use with caution in patients with a history of cardiac decompensation or hypertension. In patients with renal impairment, reduced dosage may be necessary. Prospective studies of Motrin Tablets safety in patients with chronic renal failure have not been done.

Motrin Tablets can inhibit platelet aggregation and prolong bleeding time. Use with caution in persons with intrinsic coagulation defects and on anticoagulant therapy.

Patients should report signs or symptoms of gastrointestinal ulceration or bleeding, skin rash, weight gain, or edema.

Patients on prolonged corticosteroid therapy should have therapy tapered slowly when Motrin Tablets are added.

The antipyretic, anti-inflammatory activity of Motrin Tablets may mask inflammation and fever.

As with other nonsteroidal anti-inflammatory drugs, borderline elevations of liver tests may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy. Meaningful elevations of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with ibuprofen as with other nonsteroidal anti-inflammatory drugs. If liver disease develops or if systemic manifestations occur (e.g. eosinophilia, rash, etc.), Motrin should be discontinued.

Drug interactions: Aspirin: used concomitantly may decrease Motrin blood levels.

Coumarin: bleeding has been reported in patients taking Motrin and coumarin.

Pregnancy and nursing mothers: Motrin should not be taken during pregnancy or by nursing mothers.

Adverse Reactions: The most frequent type of adverse reaction occurring with Motrin is gastrointestinal of which one or more occurred in 4% to 16% of the patients.

Incidence Greater than 1% (but less than 3%)—Probable Causal Relationship

Gastrointestinal: Nausea,* epigastric pain,* heartburn,* diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence); **Central Nervous System:** Dizziness,* headache, nervousness; **Dermatologic:** Rash* (including maculopapular type), pruritus; **Special Senses:** Tinnitus; **Metabolic/Endocrine:** Decreased appetite; **Cardiovascular:** Edema, fluid retention (generally responds promptly to drug discontinuation, see PRECAUTIONS).

Incidence less than 1%—Probable Causal Relationship**

Gastrointestinal: Gastric or duodenal ulcer with bleeding and/or perforation, gastrointestinal hemorrhage, melena, gastritis, hepatitis, jaundice, abnormal liver function tests; **Central Nervous System:** Depression, insomnia, confusion, emotional lability, somnolence, aseptic meningitis with fever and coma; **Dermatologic:** Vesiculobullous eruptions, urticaria, erythema multiforme, Stevens-Johnson syndrome, alopecia; **Special Senses:** Hearing loss, amblyopia (blurred and/or diminished vision, scotomata, and/or changes in color vision) (see PRECAUTIONS); **Hematologic:** Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia (sometimes Coombs positive), thrombocytopenia with or without purpura, eosinophilia, decreases in hemoglobin and hematocrit; **Cardiovascular:** Congestive heart failure in patients with marginal cardiac function, elevated blood pressure, palpitations; **Allergic:** Syndrome of abdominal pain, fever, chills, nausea and vomiting, anaphylaxis, bronchospasm (see CONTRAINDICATIONS); **Renal:** Acute renal failure in patients with pre-existing significantly impaired renal function, decreased creatinine clearance, polyuria, azotemia, cystitis, hematuria; **Miscellaneous:** Dry eyes and mouth, gingival ulcer, rhinitis.

Incidence less than 1%—Causal Relationship Unknown**

Gastrointestinal: Pancreatitis; **Central Nervous System:** Paresthesias, hallucinations, dream abnormalities, pseudotumor cerebri; **Dermatologic:** Toxic epidermal necrolysis, photoallergic skin reactions; **Special Senses:** Conjunctivitis, diplopia, optic neuritis; **Hematologic:** Bleeding episodes (e.g. epistaxis, menorrhagia); **Metabolic/Endocrine:** Gynecomastia, hypoglycemic reaction; **Cardiovascular:** Arrhythmias (sinus tachycardia, sinus bradycardia); **Allergic:** Serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis; **Renal:** Renal papillary necrosis.

*Reactions occurring in 3% to 9% of patients treated with Motrin. (Those reactions occurring in less than 3% of the patients are unmarked.)

**Reactions are classified under "Probable Causal Relationship (PCR)" if there has been one positive rechallenge or if three or more cases occur which might be causally related. Reactions are classified under "Causal Relationship Unknown" if seven or more events have been reported but the criteria for PCR have not been met.


Overdosage: In cases of acute overdosage, the stomach should be emptied. The drug is acidic and excreted in the urine so alkaline diuresis may be beneficial.

Dosage and Administration: Rheumatoid arthritis and osteoarthritis. Suggested dosage is 300, 400, or 600 mg t.i.d. or q.i.d. Do not exceed 2400 mg per day. Mild to moderate pain: 400 mg every 4 to 6 hours as necessary.

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References: 1. Kales J et al: *Clin Pharmacol Ther* 12:691-697, Jul-Aug 1971. 2. Kales A et al: *Clin Pharmacol Ther* 18:356-363, Sep 1975. 3. Kales A et al: *Clin Pharmacol Ther* 19:576-583, May 1976. 4. Kales A et al: *Clin Pharmacol Ther* 32:781-788, Dec 1982. 5. Frost JD Jr, Delucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. 6. Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. 7. Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther* 21:355-361, Mar 1977. 8. Zimmerman AM: *Curr Ther Res* 13:18-22, Jan 1971. 9. Amrein R et al: *Drugs Exp Clin Res* 9(1):85-99, 1983. 10. Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. 11. Greenblatt DJ et al: *Sleep* 5(Suppl 1):S18-S27, 1982. 12. Kales A et al: *Pharmacology* 26:121-137, 1983.

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Contraindications: Known hypersensitivity to flurazepam HCl; pregnancy. Benzodiazepines may cause fetal damage when administered during pregnancy. Several studies suggest an increased risk of congenital malformations associated with benzodiazepine use during the first trimester. Warn patients of the potential risks to the fetus should the possibility of becoming pregnant exist while receiving flurazepam. Instruct patient to discontinue drug prior to becoming pregnant. Consider the possibility of pregnancy prior to instituting therapy.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, light-headedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase, and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. **Adults:** 30 mg usual dosage; 15 mg may suffice in some patients. **Elderly or debilitated patients:** 15 mg recommended initially until response is determined.

Supplied: Capsules containing 15 mg or 30 mg flurazepam HCl.

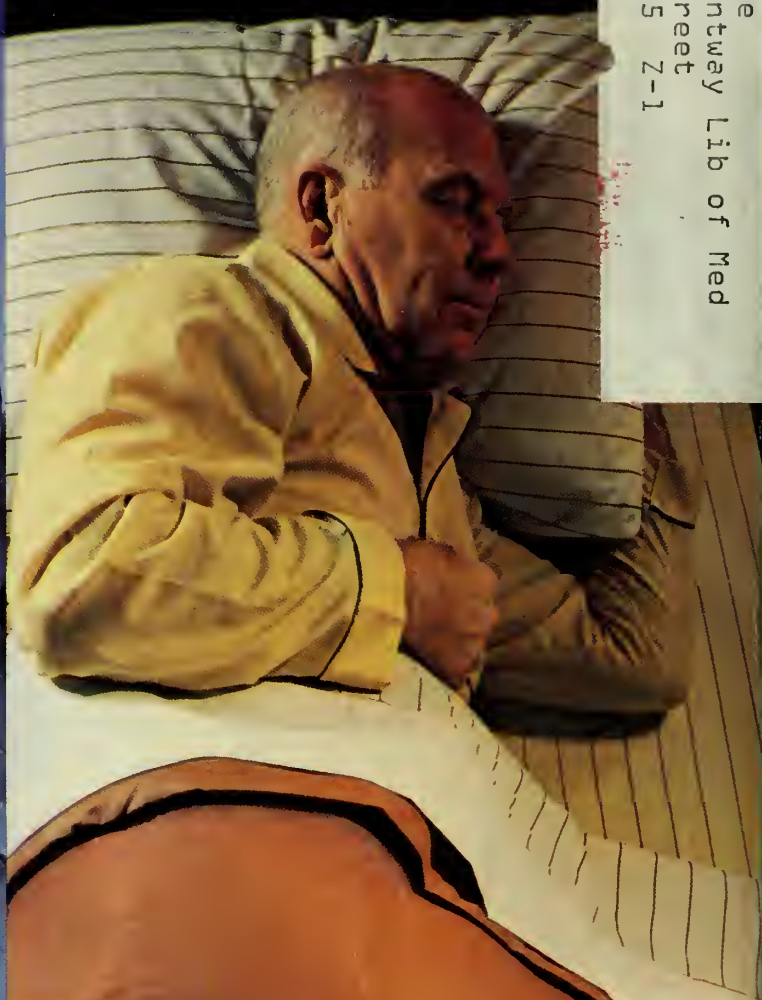


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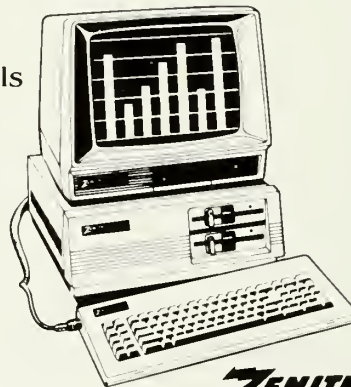
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Newsletter

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NEW PATIENT MATERIALS ON MEDICARE
FREEZE NOW AVAILABLE

DEC 27 1984

The American Medical Association produced posters and brochures to help physicians explain to patients why they have chosen not to sign a "participation" agreement under the new Medicare provisions. The attractive posters and brochures explain to patients that the changes in the Medicare law need not affect their physician/patient relationship. Sample copies of the brochure are available from the Society's office at 401/331-3207.

ALTERNATIVE SOURCES OF MALPRACTICE COVERAGE UNDER STUDY

The Society currently is investigating alternative sources of malpractice insurance to the Joint Underwriting Association (JUA), President Dr Paul J.M. Healey told the Executive Committee at its recent meeting. Drs Healey and Walter Cotter met with E. James Stergiou of the New York actuarial firm Woodward & Fondiller to evaluate such options as establishment of an off-shore company and captive carriers. A detailed report is expected early next year.

In other actions at its November 12 meeting, the Executive Committee:

- received a report on the current status of the controversial "pre-admission review" program of Health Care Review, Inc. Under the program, physicians must obtain prior approval from the professional review organization (PRO) before hospitalizing Medicare patients for approximately 100 surgical procedures. PRO and federal officials contend that the procedures may be done safely on an outpatient basis.

As the result of objections raised by the RIMS House of Delegates at its September meeting, Health Care Review agreed to postpone implementation of

EXECUTIVE COMMITTEE MEETS (continued)

approximately 20 procedures pending further review by state surgical subspecialty societies. The PRO also said that an expedited review method would be developed for patients who are to be hospitalized within one or two days of the request for prior approval.

- noted that the Society plans to establish a "key-man" program under which members will be asked to contact their acquaintances in the RI General Assembly on crucial legislative items. A survey concerning this matter has been sent to all RIMS members.
- received a recommendation from the Nominating Committee that the name of Dr Herbert Rakatansky as president-elect be submitted to the Council at its next meeting. The nomination, if approved by the Council, will be forwarded to the House for action at its next meeting. If elected, Dr Rakatansky will serve for the remainder of the unexpired term of Dr Leonard S. Staudinger, who recently resigned the position.

Dr Rakatansky, currently Chairman of the RIMS Committee on Impaired Physicians, served as president of the Providence Medical Association during 1982-1983. He is a Providence gastroenterologist.

RI HOSPITALS FACE SUBSTANTIAL HIKE

Premiums for the malpractice reinsurance program sponsored by the Hospital Association of Rhode Island (HARI) have skyrocketed 900 per cent, according to HARI officials. Ten of the hospitals in the state are insured under the program.

The total premium costs for these hospitals increased from \$290,000 for \$10 million coverage during 1982-1983 to \$2.6

HOSPITAL PREMIUMS SKYROCKET (continued)

million for the same protection next year. The coverage includes excess liability insurance for all ten institutions and the excess malpractice premiums for physicians employed by four hospitals. The rise was attributed largely to a substantial increase in premiums for physician coverage, from \$31,000 to \$1.5 million.

In a related development, St. Paul Fire & Marine Insurance Company recently issued a report based on its claims data for the years 1979 through 1983 which alleges 12 factors to be the principal causes of malpractice suits. These include surgical post-operative complications; birth-related dysfunctions; "inadvertent" surgical procedures and inappropriate surgery; failure to diagnose fracture, dislocation, and neoplasms; improper treatment of fracture or dislocation; lack of physician supervision; adverse drug reactions; failure to diagnose pregnancy-related problems; complications from infection; and improper treatment during an examination. Among these factors, claims for obstetrical complications and failure to diagnose cancer resulted in the highest average cost of settlement, at \$70,997 and \$41,883 respectively.

LOCAL PATIENT SUPPORT GROUPS FORMED

An arthritis educational support group has been established by the Roger Williams General Hospital to provide arthritis patients and their families with the opportunity to share experiences, offer support and advice to one another, and learn more about the disease. The group meets on the second Tuesday of each month and features different guest speakers and topics ranging from pain control to physical therapy exercises. Additional information is available by calling 456-2190 between 1 pm and 3pm, Mondays through Fridays.

The newly-formed Rhode Island affiliate of the National Alopecia Areata Foundation also will meet at Roger Williams on Friday, December 28, at 7 pm. The group meets monthly to provide guidance to both child and adult victims of baldness. Additional information is available from Anne Marie Iannetta at 722-2164.

TECHNOLOGICAL INNOVATIONS TARGETED AS CULPRIT IN RISING MEDICAL COSTS

Technological innovations are the "primary cause of the increase" in US health care costs, according to a report recently published by the US Congressional Office of Technology Assessment (OTA). Costs related to medical technology have contributed substantially to the 19 per cent annual increase in Medicare spending since 1974. The OTA report also noted that Medicare reimbursement policies have encouraged the growth of technology and made it available to more and more patients. "The inappropriate use of medical technology is common and raises Medicare and health system costs without improving quality of care," the report alleges. OTA staff further postulate that surgical procedures, laboratory tests, and other tests frequently are overutilized, resulting in more complex interventions and longer hospital stays.

Despite the alleged scope of the problem, however, the OTA recommends against rationing as an effective means of controlling Medicare costs and suggests instead the development of alternative health care delivery systems as the "best approach to the problem." The OTA recommendations often are used as the basis of Congressional actions on Medicare financing.

PROVIDENCE CENTER WINS NATIONAL AWARD

The Hospital & Community Psychiatry Institute of the American Psychiatric Association (APA) recently presented a certificate of significant achievement to the Center for Counseling & Psychiatric Services, 520 Hope Street, Providence. The award, one of six presented at the organization's 1984 meeting, recognizes PROJECT CHILD, which provides an intensive treatment program for the children of chronically mentally-ill parents.

PROJECT CHILD focuses on youngsters from birth to five years of age, according to Medical Director Dr Michael Ingall. "The deinstitutionalization of the chronically mentally ill has returned many patients of child-bearing age to the community," Dr Ingall said. Almost 20 per cent of the patients at the Center have children who

AWARD PRESENTED (continued)

run a 70 per cent risk of developing "severe adjustment problems by the time they reach adolescence."

To work toward preventing such problems, the program screens children of psychotic parents to detect emotional disturbances and developmental delays. Upon referral to the program, each family has a comprehensive assessment which includes a home study, preschool classroom observation if the child is in school, and various tests to measure the cognitive, language, social, and physical capabilities of the child. The family and child receive treatment services at the Center between two and five times weekly. Another feature of the program is its innovative "Baby School," where mothers learn how to interact with their infants and toddlers during play and meal times.

ADDITIONAL INFORMATION AVAILABLE ON SOUTHEAST ASIAN REFUGEES

The Rhode Island Department of Health has published a useful reference list for physicians, nurses, and other health professionals who treat Southeast Asian patients. "Southeast Asian Immigrant Health Issues: A Short Bibliography for Health Professionals," is available from Dr William H. Hollinshead, Division of Family Medicine, RI Department of Health (277-2312). The July and August issues of the Rhode Island Medical Journal featured papers on the medical, social, and cultural complications of treating this population.

PHYSICIAN OFFICE EXPENSES MOUNT

According to the Socio-Economic Monitoring System of the American Medical Association, the average total professional expenses of self-employed physicians grew by 9.6 per cent from \$78,400 in 1982 to \$83,900 last year. The rate of increase exceeded that of inflation for the same period by 5.8 per cent.

The major factors contributing to the hike were malpractice premiums, office expenses, and medical supply costs. The percentage

COSTS OF DOING BUSINESS HIGHER (continued)

increases for these items between 1982 and 1983 were 22.4 per cent, 20 per cent, and 17.9 per cent, respectively. At \$29,200 in 1983, nonphysician personnel expenses were still the largest single component. The level of personnel expenses, however, represented a decline of 3.9 per cent from 1982. This decline partially offset increases for other expense items, thus moderating the rise in overall expenses for 1983.

HMOs EXPERIENCE DRAMATIC GROWTH

According to InterStudy, a Minneapolis-based health policy research center, health maintenance organizations (HMOs) have experienced a dramatic growth during the past year, with 290 HMOs currently serving 13.6 million patients. Enrollment in HMOs increased 15.4 per cent from June 1982 to June 1983, the largest one-year single gain since 1978. The national Blue Cross & Blue Shield Association recently reported that plans sponsored by the Blues showed a 26 per cent membership increase last year.

A Wall Street research firm, Frost & Sullivan, has predicted that HMO revenues will "skyrocket in this decade." They project that the number of Medicare beneficiaries enrolled in HMOs will increase from 4 to 20 per cent. The total number of HMO patients, according to the firm, is expected to triple from 13 million in 1983 to 40 million by 1990. HMO income is expected to increase from \$9.6 billion last year to \$70 billion by the end of the decade.

PERIPATETICS

Rhode Island physicians in the news are:

- New fellows of the American College of Physicians include Drs Dennis H. Novack, Tom J. Wachtel, and Steven A. Wartman, all of Providence.
- The University of Claude Bernard, Lyon, France recently awarded the honorary doctor of medicine degree to Dr Jacques Susset, chief of urology at the Roger Williams General Hospital.

PRACTICE MANAGEMENT QUESTION OF THE MONTH:

EVALUATING CONTRACTS BETWEEN PHYSICIANS AND HOSPITALS

The increasingly competitive health care industry and implementation of the prospective payment system under Medicare have resulted in new types of economic relationships between hospitals and physicians. In response to economic pressure, many physicians and their hospitals are establishing joint ventures and other business entities for their mutual benefit. Participants may include a single hospital and its medical staff or several hospitals and their attending physicians.

The nature of the contract between physicians and hospitals depends primarily on the kind of activity which the business entity will sponsor. This may be, for example, a free-standing emergency care unit or a diagnostic imaging center owned and operated by the joint venture. Some physician/hospital entities are developing DRG incentive plans designed to offer financial awards to those physicians who provide quality medical care in the most efficient manner. The intended activity of the joint venture, which typically is established as a partnership or corporation, should be described specifically in the contract.

Before signing any contract, however, you should obtain satisfactory answers to the following:

- How will participation in the venture affect your medical practice and your ability to provide quality medical care to your patients?
- Who will be responsible for managing the venture?
- Have provisions been made for adequate representation by participating physicians on the governing board?
- What opportunities will you have to participate in the management of the venture?
- What control will you have concerning its present and planned activities and operation?
- Is your contribution to management sufficient to assure maximum benefits for your practice?
- Is the venture financially sound?
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- What are the provisions for terminating your participation? Are you required to delay selling your interest until another investor buys it?

As with any contract, the agreement between the hospital and its physicians is legally binding. It is recommended that physicians consult with their attorneys and tax advisers during their initial investigations of the joint venture.

Rhode Island Medical Journal

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COVER

The National Christmas Tree, Washington, DC. The officers and staff of the Rhode Island Medical Society and the Rhode Island Medical Journal should like to take this opportunity to wish you and your family the best of the holiday season and a happy and prosperous 1985.

Photograph provided courtesy of the office of Congresswoman Claudine Schneider.

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Extracorporeal Shock Wave Lithotripsy

Doctor George Pfister, radiologist at the Massachusetts General Hospital, recently presented to an audience in Providence* a new method of destroying renal and ureteral stones noninvasively. Hitherto, the most advanced method of non-surgical removal has been by percutaneous stone extraction through percutaneous nephrostomy using flexible or rigid endoscopes, grasping forceps baskets, ultrasonic lithotripsy, or a combination of these procedures. Chemical dissolution of some types of stones has also been possible. White and Smith have been able to remove percutaneously 95 per cent of pelvicaliceal stones and 80 per cent of ureteral stones in 200 patients by these methods.¹ Similarly, Reddy et al² have recovered 95 caliceal and otherwise poorly accessible stones from 53 patients.

Extracorporeal shock wave lithotripsy as developed in Germany is, however, totally noninvasive.^{2, 4} Although both shock waves and ultrasonic waves are governed by the same laws of acoustics, in terms of energy content they are fundamentally different. While ultrasound exhibits sinusoidal wave form, a shock wave consists of a positive pressure front of multiple frequencies with a steep onset. The shock waves give rise to mechanical stresses which break the brittle stones. The waves can be transmitted freely through the body without loss of energy if there is an appropriate transition medium such as water. They do not damage body tissues in passing through, and they can be focused by suitable reflectors. The stones are located by two independent x-ray image conversion systems arranged so that they intersect at the focus of the shock wave.

The patient, suspended in a chair in a water bath, is surrounded by the imaging equipment and shock wave generator. Cardiac arrhythmias and extrasystoles can be precipitated by the shock wave, so that triggering of the shock wave is now coupled to the R wave of the ECG, minimizing the hazard. The total number of impulses per treatment is limited to the order of one thousand. The

patient must be anesthetized. Ureteral stones behind the pelvis are not accessible. Stones that have been in the ureter longer than six weeks are usually imbedded in the ureteral wall and surrounded by a matrix of organic material and they cannot be dispersed. Pathological drainage conditions below the stone also constitute a contraindication. Large stones, particularly large staghorn stones, may not be amenable to treatment, although fragmentation may facilitate later removal by surgery or percutaneous endoscopy. The whole treatment takes about an hour and the actual radiation about one minute. Chaussy and co-workers⁵ recently reported their results in 1068 cases treated during a four-year period. Eighty-eight per cent of cases responded to one treatment. Two or three consecutive treatments were required in the remaining 12 per cent of cases. Radiological follow-up three months after treatment revealed 90 per cent of patients to be free of stones.

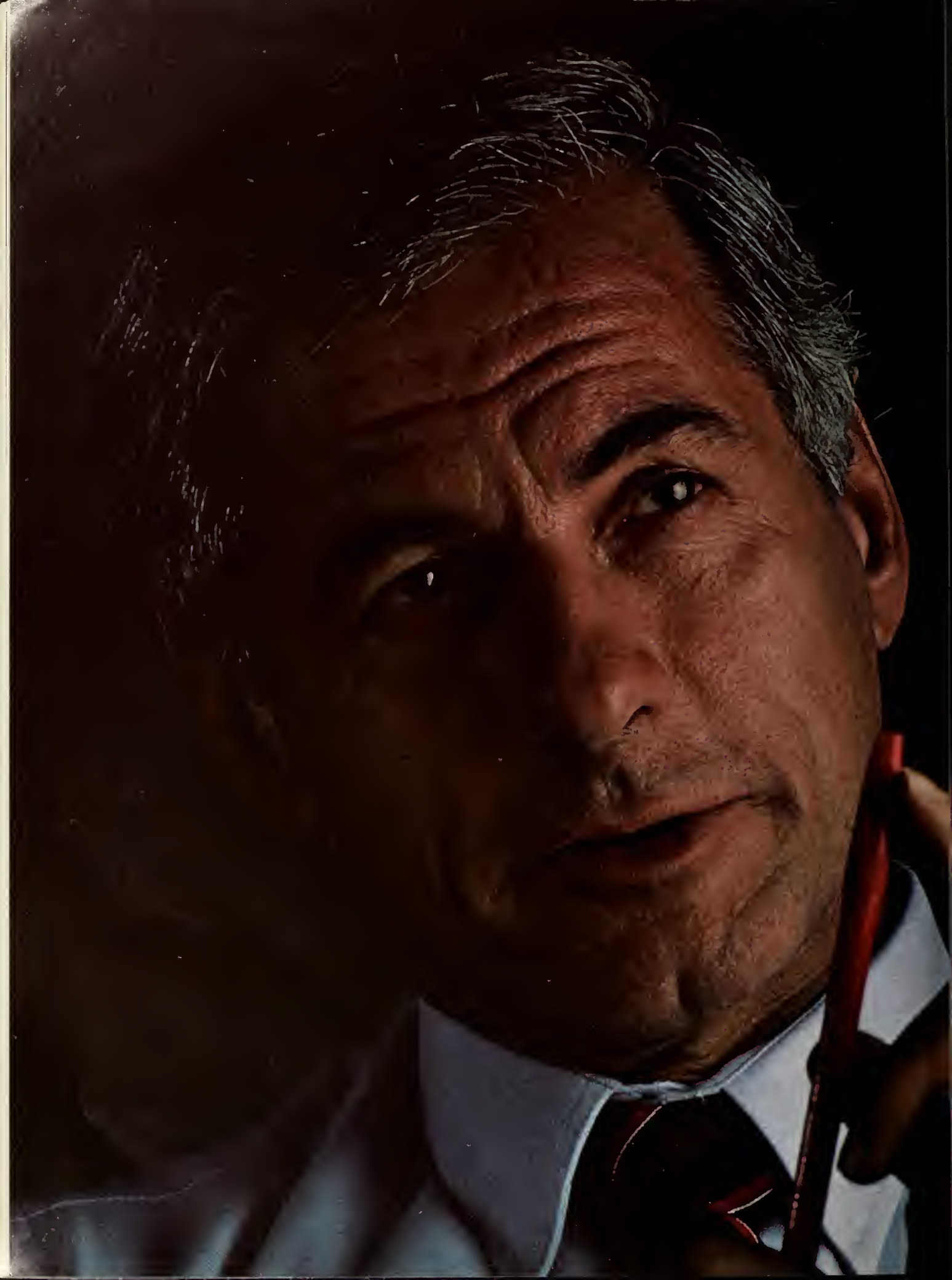
Now for the bottom line, as they say. The equipment (currently available only from Philips) costs about \$1.25 million. Preparing a room and providing the necessary support systems brings the total initial cost to about \$2 million. Considering the limited number of cases for which this new modality will be indicated, we wonder how the health planning groups in Rhode Island will respond when inevitably they receive requests for certificates of need from all over the state.

Seebert J. Goldowsky, MD

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* George Auditorium, Rhode Island Hospital, September 17, 1984.



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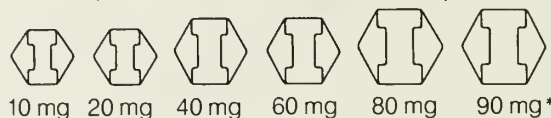
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CLINICAL PHARMACOLOGY

The Beta-Blocker Heart Attack Trial (BHAT) was a National Heart, Lung and Blood Institute-sponsored multicenter, randomized, double-blind placebo-controlled trial conducted in 31 U.S. centers (plus one in Canada) in 3,837 persons without history of severe congestive heart failure or presence of recent heart failure, certain conduction defects, angina since infarction, who had survived the acute phase of myocardial infarction. Propranolol was administered at either 60 or 80 mg t.i.d. based on blood levels achieved during an initial trial of 40 mg t.i.d. Therapy with INDERAL, begun 5-21 days following infarction, was shown to reduce overall mortality up to 39 months, the longest period of follow-up. This was primarily attributable to a reduction in cardiovascular mortality. The protective effect of INDERAL was consistent regardless of age, sex or site of infarction. Compared to placebo, total mortality was reduced 39% at 12 months and 26% over an average follow-up period of 25 months. The Norwegian Multicenter Trial in which propranolol was administered at 40 mg q.i.d. gave overall results which support the findings in the BHAT.

Although the clinical trials used either t.i.d. or q.i.d. dosing, clinical, pharmacologic and pharmacokinetic data provide a reasonable basis for concluding that b.i.d. dosing with propranolol should be adequate in the treatment of post-infarction patients.

CLINICAL. In the BHAT, patients on INDERAL were prescribed either 180 mg/day (82% of patients) or 240 mg/day (18% of patients). Patients were instructed to take the medication 3 times a day at mealtimes. This dosing schedule would result in an overnight dosing interval of 12 to 14 hours which is similar to the dosing interval for a b.i.d. regimen. In addition, blood samples were drawn at various times and analyzed for propranolol. When the patients were grouped into tertiles based on the blood levels observed and the mortality in the upper and lower tertiles were compared, there was no evidence that blood levels affected mortality.

PHARMACOLOGIC. Studies in normal volunteers have shown that a 90 mg b.i.d. regimen maintains beta blockade at, or above, the minimum for 60 mg t.i.d. dosing for 24 hours even though differences occurred at two time intervals. At 10-12 hours after the first dose of the day, t.i.d. dosing gave more beta blockade than b.i.d. dosing, at 20-24 hours the trend of the relationship was reversed. These relationships were similar in direction to those observed for plasma propranolol levels (see Pharmacokinetic).

PHARMACOKINETIC. A bioavailability study in normal volunteers showed that the blood levels produced by 180 mg/day given b.i.d. are below those provided by the same daily dosage given t.i.d. at 10-12 hours after the first dose of the day but above those of a t.i.d. regimen at 20-24 hours. However, the blood levels produced by b.i.d. dosing were always equivalent to or above the minimum for t.i.d. dosing throughout the 24 hours. In addition, the mean AUC on the fourth day for the b.i.d. regimen was about 17% greater than for the t.i.d. regimen (1,194 vs. 1,024 ng/ml·hr).

CONTRAINDICATIONS

INDERAL is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with INDERAL.

WARNINGS

CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or INDERAL should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned the dosage should be gradually reduced over at least a few weeks and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS

INDERAL (propranolol hydrochloride) should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL, like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA. Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

THYROTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS

General: Propranolol should be used with caution in patients with impaired hepatic or renal function. INDERAL is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that INDERAL may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if INDERAL is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy. Pregnancy Category C. INDERAL has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. INDERAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. INDERAL is excreted in human milk. Caution should be exercised when INDERAL is administered to a nursing woman.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to catatonia, visual disturbances, hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometric tests.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: alopecia, LE-like reactions, psoriasisiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

*The appearance of INDERAL tablets is a registered trademark of Ayerst Laboratories.

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Peer Review Is Big Business

The negotiated contract between the federal Health Care Financing Administration (HCFA) and Health Care Review, Inc, the professional review organization (PRO) for Rhode Island, with a price tag of \$1,299,846 is not insignificant.

The stated *objectives* and *outcome milestones* of the contract are of even greater significance to practicing physicians. These elements of the two-year agreement, which became effective on August 1, 1984, really address the *raison d'être* of government-financed operations for hospital utilization review and quality control. The contract's numerous provisions can be reduced to one simple equation: Medicare dollars are to be cut by denying payment for procedures which may be performed on an outpatient basis or by reducing the actual hospital admissions in specific diagnosis-related group (DRG) categories.

The push toward ambulatory care resulted in the outpatient surgery list which was promulgated last September. This list of some 58 procedures, which require prior authorization for hospitalization, created a furor and unleashed a barrage of letter writing to the PRO. It was a major agenda item of the RIMS House of Delegates at its September 19 meeting, resulting in the appointment of an ad hoc committee to meet with officials of Health Care Review. As a result of the meeting, 18 procedures from the initial list were deleted temporarily. After further consultation with surgical specialty societies, the PRO has published a modified list which eliminates 10 surgical procedures. The remaining eight will require pre-admission authorization, either by letter or completion of an outpatient surgery form which documents the specific medical reasons for hospitalization. Among the eight are hemorrhoidectomy, herniorrhaphy, and cataract extraction.

But why a list in the first place? Quite simply, because the initial objective of the PRO contract is the elimination of an estimated 1,114 inpatient hospital admissions in Rhode Island relating to the 58 procedures (now 48) listed in Health Care Review proposal. PRO claims that these procedures can be performed "safely and effectively in the ambulatory setting."

The second objective is the reduction in hospital admissions by almost one-third, or nearly 600 in all, in ten specific DRG categories: 24 (seizures), 25 (headaches), 65 (disequilibrium), 188 digestive disease diagnoses), 243 (back problems), 325 (kidney dysfunctions and urinary tract infections), 395 (red blood cell disease), 410 (chemical dependency), 433 (alcohol-related dysfunctions), and 437 (other substance abuse problems). The results will be evaluated on a quarterly basis. Another objective is the reduction in the number of Medicare patients admitted for permanent pacemaker insertions by 200. The contract also proposes reducing the number of admissions to rehabilitation units for fractured hips and eliminating 100 admissions to Zambano and Rhode Island Medical Center.

Moreover, parts of the contract also deal with the quality of medical care. Specifically, there are *five quality objectives*: reduction of Medicare readmissions within seven days of premature discharge; 50 per cent reduction in the number of avoidable deaths among Medicare patients with pulmonary emboli; reduction by 9 per cent the number of Medicare patients in whom temporary or permanent pacemakers were unnecessarily placed; and reduction of postoperative urinary tract infection by 40 per cent of patients with indwelling Foley catheters.

It should be noted that Maine also must deal with comparable objectives. Health Care Review, Inc of Rhode Island recently signed a two-year contract worth \$1,650,000 to perform PRO services for that state. This is indeed a large order.

Obviously, there is much more to a 50-page contract than this brief summary would indicate. It also covers documentation procedures, review summaries, progress reports, PRO review activity, denial determination, sanction activity reports, and the required delivery schedule. While the entire process would appear to be a monumental undertaking, it must be done because of the dictates of federal law. HCFA believes that it is worth \$1,299,846 to accomplish these objectives in Rhode Island.

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Of course, not every stock on each list has performed well, and past overall success is no guarantee of future performance or of how any single recommendation fared. Still, we are proud of our results and would be happy to send you our latest Progress Report which includes our Current Special Research Series recommendations.

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Medical Education: Past, Present, and Future

Medical Education Must Be Adequately Funded to Provide Efficient High Quality Health Services to All

John I. Sandson, MD

While few would disagree that in 1983 the United States is the leading center of medical education in the world, it was not until after World War II that the nation began to receive recognition as the outstanding site of medical education.

An Historical Overview

In the early colonial days medical education was in the apprentice mode.¹ Some of the better-trained physicians spent time in Europe, in the very early days in Padua or Leyden and later in Edinburgh, Paris, London, or Vienna. The first medical school and teaching hospital was started in 1765 in Philadelphia at the College of Philadelphia, later to be reconstituted as the University of Pennsylvania. The second medical school was founded in 1768 at Kings College, New York, the predecessor of the College of Physicians and Surgeons; and the third came into existence in Boston at Harvard University in 1782.

The nineteenth century saw many medical schools, a total of 400, come and quickly depart from the scene. Many of these schools were not of high quality, and some were truly diploma mills. Prerequisites for admission were minimal, coursework was poor, clinical training was often absent, and laboratory instruction was limited. During the latter half of the century there was considerable interest in medical education for

women. During this period, 16 schools of medicine for women were established.

By 1900 there was much dissatisfaction with the state of medical education. As the basis for his famed analysis, Abraham Flexner in 1910 visited most of the 135 medical schools then in existence and carefully analyzed his findings. After reporting on the gross deficiencies of many of these schools, Flexner recommended such sweeping reforms as closer affiliations between medical schools and their universities, full-time faculty in the basic sciences, carefully-supervised clinical experiences, and substantial prerequisites for admission. Shortly after publication of the Flexner report, the number of medical schools declined to 75. For the most part, the quality of the remaining institutions was reasonably good.

Gradually over the next three decades, medical schools as we know them today began to evolve. Full-time faculty became the rule in the basic sciences, university hospitals were developed, and most medical schools became affiliated with a parent university.

Development of medical education has progressed more rapidly in the last four decades than in all prior years.² Large, highly sophisticated medical schools with excellent teaching hospitals have evolved. The number of medical schools and the number of medical students have increased substantially. There currently are 127 medical schools with more than 17,000 medical students admitted each year.

There are several explanations for this enormous growth during the past 40 years. First is the important role played by the medical schools in biomedical research. Large-scale research started after World War II and expanded in a very dramatic fashion with the National Institutes of Health (NIH) budget increasing over fifty-fold,

This paper was presented in part at the Oration on Medical Education, The Miriam Hospital, Providence, Rhode Island, October 19, 1983.

John I. Sandson, MD, Dean, Boston University School of Medicine, Boston, Massachusetts.

rapidly making this country the world leader in this important realm. To continue this role, medical schools significantly expanded their faculties and their physical facilities. Secondly, beginning in the 1960s, medical schools were given a mandate and fiscal incentives to expand their facilities to meet a perceived shortage of physicians.³ While that shortage is now being questioned, these incentives were effective. The number of medical schools has increased from 85 to 127 and entering students from 7,500 to 17,000 during the past 25 years.⁴ Thirdly, medical care has become more sophisticated and highly technological. Much of the complex medical care has become concentrated in the academic medical centers with their availability of high technology, clinical specialists, physician investigators, and other personnel.

American medicine and medical education is now in its Golden Age. Students from abroad wish to come here to study. Patients from all over the world want to be treated in the United States. But what about the future?

The Future of Medical Education

My first concern relates to the future of independent (ie, private) medical education. Approximately 50 of the 127 medical schools are private institutions. The actual cost of medical education is very high, now averaging about \$24,000 per student each year. Yet tuition for state residents in almost all tax-supported medical schools is under \$4,000, averaging about \$2,500, while tuition in some independent medical schools is \$19,000, averaging about \$12,000 in 1983-84.⁵

It is likely that students starting in a private medical school in 1983 may well borrow a total of \$100,000 while still in school.⁶ Who can afford that size debt at such an early stage in life? Who will choose to attend an independent medical school? Even in public medical schools, the debt, which averages approximately \$60,000 per student, will not be negligible.

At the very best, the socio-economic mix of the student body at medical schools probably will change. The independent schools could become the province of the wealthy, especially if tuition reaches \$20,000-\$30,000 annually by the end of this decade. At the worst, private medical schools may be priced out of existence. This could begin to occur at the point at which the quality of the student body deteriorates as a result of high tuition levels. As long as medicine remains attractive as a career and assuming that there is no signifi-

cant expansion of public medical schools, the private institutions probably will continue to attract qualified students. If medicine as a career becomes less financially attractive, it is likely that the private medical schools will encounter serious difficulties and that some will not survive.

Another concern is that most medical schools, even public facilities, depend heavily upon the National Institutes of Health and other federal sources for support of their research programs. If this support were to disappear and sufficient alternative funding were not found, the research performed by medical schools would be decreased markedly. These research programs are essential to maintaining the high quality of medical faculties and medical education programs. While federal funding for biomedical research has not been drastically cut, it has barely kept up with inflation. Just as worrisome is the sparse support for research training. Without the training of new physician scientists and other biomedical investigators, the future of biomedical research will be bleak indeed.

Some medical schools have sought research support from industry. However, it is unlikely that industry can replace the \$4.2 billion provided each year by NIH. It is also doubtful that industry will choose to award many grants on the basis of a merit peer review process. Although support from industry may prove to be helpful, it is essential that the federal government continue to support biomedical research vigorously. Funds for research and research training must be increased in significant real terms.

A third concern relates to the proposed cutbacks in medical care costs and the effects of these reductions on the quality of health care and medical education. Academic medical centers and teaching hospitals are being blamed for increasing the costs of health care, primarily through the allocation of many teaching costs to patient care expenditures. Most instructional costs in teaching hospitals can be related primarily to residency programs. These costs are usually more than offset by specific patient care services provided by residents. It is likely that the very high costs in academic centers are due to the severity of illness and the sophisticated technology required than to teaching costs.

There is reason to be concerned that skyrocketing medical costs will lead to efforts to eliminate "teaching costs" without providing an alternate source of funds to pay for residency programs. As most medical students completing medical school are heavily in debt, it is unreasonable to try

Table 1. — Total Repayment for \$40,000 (\$10,000/year) HEAL Loans

Interest Rate	Repayment Schedule		
	10 years	15 years	25 years
12%	\$148,080	\$185,940	\$271,800
15%	\$200,880	\$261,360	\$398,700
18%	\$270,120	\$362,160	\$568,800
21%	\$360,240	\$494,820	\$792,600
24%	\$476,760	\$667,620	\$1,083,900

Table 2. — Revolving Loan Fund*

Year	Debt	Annual Interest	Monthly Payment
1	\$ 5,000	2%	—
2	10,100	2%	—
3	15,202	2%	—
4	20,304	2%	—
5	20,304	6%	\$172.58†
6	19,289	6%	\$172.58
7	18,274	6%	\$172.58
8	17,259	6%	\$172.58
9	16,244	6%	\$172.58
10	15,228	10%	\$317.25‡
11	12,183	10%	\$317.25
12	9,137	10%	\$317.25
13	6,092	10%	\$317.25
14	3,046	10%	\$317.25
15	0	—	\$29,390 total repayment

* \$5,000/year for four years

† 6% interest plus 5% principal/year

‡ 10% interest plus 15% principal/year

to pass these costs on to either residents or medical students. Without residency programs, academic medical centers would change drastically. They would be less stimulating and probably less able to deliver quality tertiary care.

Quality of Medical Education

Although most medical schools in this country are rated as good to excellent, medical education is frequently criticized by faculty and medical students alike. There are major efforts at most schools to evaluate the effectiveness of the curriculum and the faculty. Curriculum committees are seeking to improve the medical education process by focusing more attention on physical diagnosis, interviewing techniques, and clinical judgment. Subjects such as geriatrics, nutrition, occupational health, law and medicine, medical sociology, medical technology, health policy, health planning, and health care delivery systems

are being introduced in more and more medical schools.

Once again, medical students are being taught to become discriminating in their use of technological innovations and to rely on their own judgment. They are learning to order essential tests only. The question of the faculty is changing from "Why did you forget to order this test?" to "Why did you order that one?" Because the base of essential biomedical information is changing quickly, more emphasis must be placed on self-learning with special attention to critical evaluation of the literature. As the importance of computers in medical practice becomes more significant, students will have to become familiar with their use.

Over the past 20 years, medical schools also have addressed the problems of geographic and specialty maldistribution. There already has been a significant increase, currently more than 50 per cent, in medical school graduates seeking training in the primary care specialties. This represents more than the total number of medical students who graduated each year during the early 1960s. Preliminary data also indicate that the geographic distribution of physicians may be improving dramatically. It is of interest to note that the number of primary care physicians is increasing just as the marked expansion in medical school class size is beginning to be felt in practice. Further improvements will be seen if reimbursement policies are changed to include incentives for physicians to seek training in primary care and other needed specialties and to practice in underserved areas.

Changes in the Medical School Curriculum

There are several important curricular experiments underway in medical education. Early selection programs were initiated by many medical schools during the 1960s. After 20 years of experience with these programs, it is evident that many have achieved their principal objectives, including: 1) the successful selection of medical students after completion of high school; 2) the adequate preparation of students for medical school in two to three years of college; and 3) the provision of a well-rounded liberal arts education in both the sciences and the humanities during the college experience. In view of the large debts incurred by most medical students, the elimination of two years from the educational continuum may become increasingly important.

There are also experiments aimed at improving the college and medical school education

process.⁷ The objectives of these programs include: 1) improving both the liberal arts and basic medical science education; 2) reducing the level of anxiety associated with the medical school application process by providing for early selection after two years of college; 3) relaxing the intense basic medical science curriculum by permitting double credit for basic medical science courses taken during college; and 4) providing the opportunity for a variety of electives early in the medical school experience.

The Boston University School of Medicine also is experimenting with an option that permits decompression the basic science curriculum. Any student may apply to take the first, and possibly the second, year of medical school in two calendar years rather than one. Half of the regular tuition is paid for each year. This program should be helpful to some students who have a background in the humanities and to those who wish to proceed at a slower pace for other reasons, including part-time employment.

Financial Considerations

The greatest challenge for medical schools in the 1980s will be to keep our institutions open to students from all segments of society. More and more students are forced to borrow a growing proportion of their educational expenses from the Health Education Assistance Loan program.⁶ In 1981-1982, loans from this program were 110 per cent larger than the previous year. The trend in financial assistance clearly is moving away from grants and toward loans guaranteed by the federal government. The types of loans may prove more important to most students than the total amount borrowed. In general, subsidized low-interest loan programs such as Guaranteed Student Loans and Health Professions Loans require repayment over a ten-year period, starting after completion of residency training. The "payback" is approximately 1.5 times the amount borrowed. After considering the impact of inflation, this means the student probably will pay back no more than was originally borrowed.

On the other hand, the Health Education Assistance Loan program can lead to onerous debt. Every dollar borrowed through this program may require repayment of up to approximately \$10 at interest rates of 15 per cent (Table 1). If present trends continue during the next five to ten years, much of the increase in tuition and living expenses will have to be borrowed through

Table 3. — Loan Plan A: Additional Capital Kept Constant at \$350,000

Year	Annual New Loans	Annual New Capital	Total Loans Outstanding
5	\$ 350,000† (367,000)	\$350,000	\$ 1,228,000
15	875,000	350,000	7,000,000‡
25	2,188,000	350,000	17,500,000
35	5,469,000	350,000	43,750,000
45	13,672,000	350,000	109,375,000
55	34,180,000	350,000	273,438,000

* Increased at a rate of 2.5 times each decade

† Projected at 95.2%

‡ Projected at 8 times the amount of new loans

Table 4. — Loan Plan B: Additional Capital Increased at the Same Rate As Tuition (Projected at 10% Annually)

Year	Annual New Loans*	Annual New Capital	Total Loans Outstanding
5	\$ 350,000† (367,000)	\$ 442,000	\$ 1,228,000
15	2,076,000	1,144,000	11,415,000\$
25	12,308,000	2,963,000	67,692,000
35	72,985,000	7,675,000	401,416,000
45	432,800,000	19,879,000	2,380,398,000
55	2,566,501,000	51,486,000	14,115,756,000

* Increased at a rate of 5.93 times each decade

† Projected at 95.2%

‡ Increased at a rate of 10% annually (2.59 times each decade)

\$ Projected at 5.5 times the amount of new loans

the Health Education Assistance Loan program. It is likely that the composition of the student body in private schools may change until most of the students come from affluent families. In the mid-1970s students from lower-middle and middle-income families dropped from 21 per cent to 11 per cent of entering medical students.⁸ The enrollment of minority students in medical schools peaked in 1974-1975 at 10 per cent. It is of interest to note that a significant number of the medical schools which have been successful in recruiting minority students are independent and have high tuition levels. If tuition continues to escalate and financial aid to decrease, it is possible that fewer minority students will choose to attend these institutions. Because it is not certain that the current number of these students will be able to gain access to public schools, the decrease in meaningful financial aid programs may well cause the number of minority students enrolled in medical schools to decline.

Independent medical schools must initiate

programs to provide more student loans from their own institutional resources. By establishing student revolving loan funds (SRLF), medical schools could provide most of the necessary loans at low-interest rates. Although these funds utilize the basic principles of the Tuition Advance Fund developed by Doctor John Silber, private capital instead of government monies are utilized. Student revolving loan funds will grow in value like money in a bank account at compounded interest.

A student revolving loan fund charging two per cent interest to the student during medical school and requiring payment of five per cent of the principal and six per cent of the interest each year during the first five years after graduation, and 15 per cent of the principal and 10 per cent of the interest annually during the next five years would require total repayment of only \$1.50 for every dollar borrowed (Table 2). Assuming a default rate of approximately five per cent and administrative costs of two per cent, such an SRLF would increase approximately 2.5 times each decade if the amount of new capital added each year were constant (Table 3). If the new capital were increased at a rate of ten per cent each year, or approximately the same amount as expected tuition increases, the SRLF would grow approximately six times each decade (Table 4).

At the Boston University School of Medicine, a commitment has been made to deposit an amount of capital equal to at least five per cent of the total tuition income into an SRLF each year. The capital will come from gifts from alumni, foundations, and corporations, as well as from tuition. The projected growth of this type of SRLF at an average-size independent school is remarkable. These schools will be able to remain open to students from all segments of our society by providing enough funds from SRLFs to meet their financial assistance needs. The diversity of students will assure that graduates of private medical schools continue to address important issues related to cost containment and improve access to health care.

Future Trends

Medical education cannot function in a vacuum. It influences and is influenced by changes in the health care system. In many ways, the higher costs of medical education reflect the extraordinary expansion of health care services that has occurred since 1965. The past twenty years have seen the implementation of Medicare and Medicaid, the upgrading of many medical facilities, and

the development of comprehensive employer-sponsored health insurance programs. During the same period, medical care progressively became more complex, technologically advanced, and expensive.

Has the increase in health care costs been excessive? During the period from 1967 to 1981, expenditures for medical services increased from \$51 billion to \$287 billion, and from 6.4 per cent to 9.8 per cent of the gross national product. From 1969 to 1975, the United States had a lower real average rate of increase than Australia, Canada, West Germany, Finland, France, the Netherlands, and Sweden. The rate of increase recently has shown signs of moderating. During the period from 1980 to 1982, the average annual real rate of growth for medical expenditures has been reported to be approximately 2.2 per cent. While not excessive, health care costs in the United States are substantial and increasing more than \$30 billion annually.^{11, 12}

As medical care represents a substantial national investment, the following steps may be helpful in obtaining quality health care at an affordable price for all: 1) The products in health care should be differentiated; 2) The medical care services that are essential should be carefully delineated. The societal debate on health care should be focused on the definition of essential services; 3) Essential medical care services must be priced on a national basis with regional adjustments. While physicians must play a role in the process, they should not have unilateral control of setting these prices; 4) Government should be committed to providing essential medical care services to the elderly and the poor. Incentives should be provided to patients and physicians to insure proper utilization of these services; 5) Employers should be committed to offer insurance coverage for essential medical care services. Other "non-essential" and more costly medical services, however, should not be covered by this insurance; 6) "Non-essential" and higher-priced medical care services should be paid by the patient or covered under special insurance policies. Physicians should determine the prices of these services; 7) The costs of health care for uninsured patients and graduate medical education should be paid on a national basis by adding a surcharge to the price of all medical services; and 8) A realistic amount for capital requirements should be included in the price for all hospital services.

Despite considerable efforts, the goal of one class of health care for all remains to be achieved. The proposal to differentiate the products in the

health care market may be the best way to insure equitable access, variety, efficiency, quality, and cost effectiveness in health care for a society functioning under free market conditions. It would require physicians to provide different kinds of products (ie, moderately-priced essential services and various levels of more costly care), insure the availability of quality essential health care to all, and make individual expenditures for "non-essential" health care a matter of personal financial consideration.

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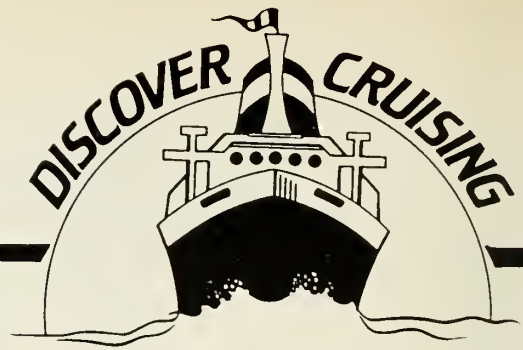
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An Analysis of the Fourth Year of Medical School

Medical Students Appear to Choose Their Elective Courses Reasonably and Generally Avoid Premature Specialization

Stephen R. Smith, MD

The Association of American Medical Colleges (AAMC) in 1966 authorized a study of the total process of physician education. Many medical schools at the time were planning significant changes in the curriculum, including the increase of elective and free time.¹ The concept of allowing considerable elective time within the medical curriculum then was quite controversial. A number of papers appeared in the literature during the early 1970s describing the new elective programs at various medical schools and advocating their continuation.²⁻⁶

A decade later, a predominantly elective fourth year has become the standard in most United States medical schools. In more than 30 institutions the fourth year is entirely elective. Students choose their elective courses based on a desire to complete missing knowledge, to prepare better for tentatively identified careers, to explore other possible career interests, to help in deciding upon residency programs, and to work with highly popular or stimulating faculty members.⁵⁻⁶

At the Brown University Program in Medicine, where the fourth year is entirely elective, a number of faculty members expressed their concerns at curriculum committee meetings that students were not utilizing the elective fourth year well. The faculty believed that students were selecting

too many electives in the fields of their prospective residencies, thus prematurely narrowing their professional education. Also expressed was the belief that students were using electives, to an excessive degree, to visit residency programs in other states. The level of supervision at clinical sites outside of the Brown elective system was also worrisome. Faculty members from other medical schools voiced similar reservations at a symposium on the role of elective courses held at the 1983 AAMC Annual Meeting.

The purpose of this paper is to present a quantitative analysis of the manner in which the class of 1982 at the Brown University Program in Medicine utilized their fourth year of medical school. New techniques of classifying electives were utilized to answer the questions posed by the faculty.

Methods

The previously cited references have catalogued the electives chosen by medical students by department. In this study, the fourth year course selected by each medical student was classified retrospectively according to the type of residency the student intended to enter. The classification system is described in Table 1. Students who did not plan to enter a residency program in 1982 were excluded. The analysis included students who intended to enter a residency immediately after graduation, but did not. Some residency programs, such as psychiatry, require a preliminary year of a flexible or internal medicine residency. In these cases, the intended field of specialization, rather than the transitional residency, was used to classify courses.

Each student's record was reviewed to ascertain the number of weeks spent in each course. For

From the Brown University Division of Biology and Medicine, Providence, Rhode Island

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"full immersion" clinical courses the actual number of weeks was used as a weighting factor. Each single credit semester-length course was considered to equal a four-week "full immersion" clinical course. As four semester-length courses were equivalent to four one-month clinical courses, this provides a fairly accurate description of the average course load during a single semester.

Courses taken at other institutions not listed in Brown elective catalogue were defined as "away" electives. The same criteria were used to determine a weighting factor based on the number of weeks spent in each "away" elective.

Results

The Class of 1982 consisted of 63 graduates. Three students were excluded from analysis since they did not intend to start their postgraduate residency training in 1982. Table 2 shows the frequency, unweighted and weighted, of the types of courses selected by the 60 other graduates during their elective fourth year.

Contrary to the expected results, the courses most commonly selected by students were clinical electives not related to their eventual specialties. This choice accounted for nearly half the courses when measured by unweighted frequency and only slightly less when corrected for the actual number of weeks. The mean value of the types of courses was 3.35. The average length of a single course was 4.08 weeks.

Students are permitted to defer required core clerkships until their fourth year. These courses

were responsible for nine per cent of unweighted course selection. Since core clerkships are longer in duration than the average four-week clinical elective, they account for a larger share of the total fourth-year time (13.6 per cent) when this factor is considered.

The mean values of the courses selected by students intending to pursue residencies in internal medicine, surgery, and all other specialties were significantly different as shown in Table 3. The mode for students planning to enter residencies in internal medicine was 3 (clinical elective related to specialty), while the mode for students planning to enter residencies in surgery or one of the other specialties was 4 (clinical elective not related to specialty). The 27 students who entered internal medicine programs chose 92 courses classified as 3, and 74 courses classified as 4.

Brown University offers a combined degree program, the Medical Education Program (MEP), in which students are admitted from secondary school and complete their baccalaureate and medical education in a seven or eight year continuum. Thirty-two of the 60 subjects were MEPs. The mean value of the courses selected by MEPs (3.23) was not statistically different from the other students (3.24).

Table 4 displays the frequency of elective courses taken elsewhere. Half of the students took no such electives at all. The total of 67 electives taken outside the Brown system represents 13.7 per cent of all fourth-year courses. Of the 30 students who took at least one such elective, three did so at an Armed Services hospital to fulfill their active duty requirement as military scholarship recipients. These Armed Forces electives represented the only such elective for the three students.

Also among the 30 students taking electives elsewhere were three students who received special permission to take the fourth year at another

Table 1. — Criteria for the Classification of 4th Year Medical Students According to Anticipated Residency Program

Classification	Criteria
1	Required core clerkship in community health, medicine, obstetrics-gynecology, pediatrics, psychiatry, or surgery
2	Clinical elective in anticipated specialty, including subinternships and advanced clinical clerkships
3	Clinical elective related to anticipated specialty, including subspecialty clinical electives
4	Clinical elective not directly related to anticipated specialty
5	Non-clinical, health-related courses, including research, basic science, epidemiology
6	Non-clinical electives that are not directly related to health, including liberal arts courses

Table 2. — Frequency Distribution of the Types of Courses Selected by 4th Year Medical Students

Course Classification	Unweighted		Weighted	
	Number	Per cent	Number	Per cent
1	44	9.0	270	13.6
2	40	8.2	157	7.9
3	137	28.1	541	27.2
4	238	48.8	884	44.4
5	27	5.5	129	6.5
6	2	0.4	8	0.4

Table 3. — Mean Value of the Type of Course Selected Categorized by Anticipated Residency Program

Anticipated Residency Program	Mean
Internal medicine	3.09*
Surgery	3.32*
Other training programs:	3.38*
Family practice	3.44
Obstetrics/gynecology	3.98
Pathology	3.03
Pediatrics	3.01
Physical medicine & rehabilitation	3.07
Psychiatry	3.17
Radiology	3.47

* p value < .05 by one-way analysis of variance

Table 4. — Frequency Distribution of Electives Taken Elsewhere by 60 4th-Year Students

Number of Outside Electives	Students	
	Number	Per cent
0	30	50.0
1	18	30.0
2	6	10.0
3	1	1.7
4	0	0.0
5	1	1.7
6	1	1.7
7	2	3.3
8	0	0.0
9	1	1.7

institution because of compelling personal reasons, such as a gravely ill parent or a spouse living in another state. These students took five, six, and nine such electives each.

Finally, Brown medical students may enroll in the Harvard University School of Public Health in place of fourth-year elective courses at Brown. Two students participated in this program and accounted for seven such electives each.

When these categories of students are excluded, the total number of electives taken elsewhere is reduced to 30.

Discussion

This analysis of the fourth year courses selected by the Class of 1982 at the Brown University Program in Medicine contrasted sharply with the expected results. The data suggest that fourth-year medical students do not prematurely narrow

their planned specialty. Students intending to enter internal medicine programs select more electives related to their eventual specialty than do students choosing other specialties. This is related to the fact that clinical electives in internal medicine subspecialty fields, such as cardiology, pulmonary medicine, and infectious diseases, are highly popular among all students.

Also surprising was the frequency of electives taken elsewhere selected by the students. Although the subjective feeling among faculty was that fourth-year students frequently completed their elective courses at other institutions, the data do not support this belief.

This analysis indicates that fourth-year medical students choose their electives in a reasonable fashion, generally avoid premature specialization, and do not abuse the freedom of the elective program as a vehicle for extensive travel. The data do suggest, however, that students planning to enter residencies in internal medicine should be advised to diversify their elective choices more extensively in other fields. The methodology employed in this analysis, in which courses are classified according to eventual specialty choice, offers significant advantages over a simple enumeration of courses by department. Subjects for further study include an analysis of the third-year courses selected by students who postponed a mandatory core clerkship until their fourth year. A continuing year-by-year analysis will be necessary to detect any emerging new trends in course selection preferences.

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Should We Welcome For-Profit Hospitals to Rhode Island?

It Is to Be Hoped That This Trend Will Be Resisted

H. Denman Scott, MD

Before addressing my principal topic, I will share with you some of the reactions I have received concerning my move from private practice into the public sector. While most people have been supportive and encouraging, I have noticed some individuals shaking their heads in disbelief. Probably the most common reaction has been "you ought to have your head examined," followed closely by "you are too young." Presumably they do not mean that I lack the experience for the job, but rather that I am not old enough to "retire" into some comfortable government post. This attitude suggests that public service is an excellent opportunity for personal relaxation. Finally, a few have wondered how a seemingly honest person like myself could get mixed up in a governmental atmosphere saturated with self-seeking, venal behavior. In short, how could I leave a professional situation in which I enjoyed much respect and success and enter an arena which has scant public confidence. During this transition period I have experienced the paradox described by a prominent sociologist, Theodore Caplow: "Americans distinguish sharply between their personal situations, which please most of them much of the time, and the state of the nation which displeases many of them most of the time."¹

Distrust of Public Institutions

This distrust of public institutions has led me to

Based on presentations at the annual meetings of Butler Hospital, Providence, and South County Hospital, Wakefield, in January 1984.

H. Denman Scott, MD, Director, Department of Health, State of Rhode Island, Providence.

review the seven deadly sins, especially as I apparently will bear witness to many of them. It is a sobering list to which most of us fall prey in one way or another: vainglory or pride, covetousness, lust, envy, gluttony, anger, and sloth. Fortunately there are the counterpoint virtues, also seven in number: prudence, temperance, fortitude, justice, faith, hope, and love. We regularly see behavior illustrative of all fourteen characteristics. Many obviously see government activity more tainted with sins than blessed by virtues. On the other hand, people seem to judge private enterprise less harshly, perhaps because of the very privacy itself. What you do not know, you cannot judge. Neither public nor private action is wholly good or entirely bad. It is imperative that we appreciate that goodness can and does get expressed through public institutions. Regrettably this manifestation is obscured, and even obliterated, by outrageous behavior and overt crime from time to time.

Because a number of persons have raised with me the issue of ethical conduct in government, I feel compelled to address it and make clear my commitment to practicing the virtues and controlling the sins.

If the chairman of the Hospital Corporation of America were being nominated as the next president of South County or Butler, we would all sense a very different atmosphere than the one here today. Fortunately this is not the case, nor, as far as I know, is it an immediate issue for any of our other voluntary hospitals. As a result, we have an opportunity to discuss the merits and drawbacks of this type of hospital ownership and to reflect on how we should respond if and when a serious proposal emerges.

Proprietary hospitals are not new. What is comparatively recent is the rapidly-expanding

national and international chains of hospitals, the best known of which is the Hospital Corporation of America, a Nashville-based concern. It has grown rapidly over the past 15 years and currently owns more than 370 hospitals with 53,000 beds. Its annual revenues are more than \$3 billion, three times the budget of the State of Rhode Island. Wall Street has looked with great favor on its stock. This corporation and similar organizations convey the message that they can provide the good old American know-how, the managerial expertise, and the entrepreneurial zeal needed to cope with the health care crisis. They will not only save taxpayers money through efficient management, but they will become taxpayers themselves. In the process excellent care will be provided and access to capital funds will be assured when needed.

If these claims are true, why do many communities find the prospect of proprietary hospital ownership an unsettling phenomenon? Doctor David Rogers, President of the Robert Wood Johnson Foundation, cited one reason for this discomfort in a recent interview: "I still have great personal difficulty in thinking about health care services as commodities to be sold for profit . . . I am upset in contemplating a system of medicine which becomes an indistinguishable part of a for-profit society."² The best practice of medicine transcends the "bottom line" orientation of the for-profit sector. Moreover, first-rate care is provided in many instances when clearly no profit can be made. The difference between the two modes of operation is also reflected in the titles conferred on board members. The trustees of voluntary hospitals not only are responsible for the financial integrity of the institution, but also must assure the public of needed institutional services. The directors of for-profit hospitals, on the other hand, must protect the equity of their stockholders. Of course, the interests of stockholders usually depend upon creditable service in order to sustain financial performance. This subtle but important distinction in governing perspective is not to be dismissed or cast aside lightly.

I want to be perfectly clear that I highly regard the entrepreneurial spirit, and have great respect for a hefty bottom line. But that spirit should reside with IBM, General Motors, General Electric, and our many other fine businesses, and not with our hospitals.

McLean Hospital

One of the most celebrated controversies regarding the for-profit issue occurred last year when

the Board of Trustees of Massachusetts General Hospital (MGH) proposed selling McLean Hospital to the Hospital Corporation of America. McLean Hospital, as part of the MGH trusteeship, is a respected psychiatric teaching hospital of Harvard Medical School. The issue was hotly debated. Ultimately, pressure from the public and professionals convinced the MGH trustees to discontinue the plan. While Francis Burr, Chairman of the MGH trustees, attempted to convince the doubters that all necessary safeguards for protecting academic freedom and assuring quality care could be incorporated into an agreement, his own ambivalence about the for-profit sector is expressed in one of his apologies: "It also was important that the purchaser wanted to buy the McLean Hospital for the right reason, ie, not to make money out of it, but to enhance the reputation of the company by preserving the quality of patient care, teaching, and the 'academicity' of the institution."³ How ironic that the company should suppress its profit motive in Boston. I also wonder at the reaction of the professional staff to being a potential "loss leader" for the corporate empire.

At the same time in Portsmouth, New Hampshire another scenario was occurring, this time with HCA consummating an agreement to buy the principal community hospital, long under the stewardship of a voluntary board of trustees. Many regretted the decision of the trustees, and concern was expressed that control would be abrogated to HCA headquarters in Nashville. An HCA official tried to assuage this concern, according to the *Boston Globe*, by claiming that "the fear of losing local control should not be an issue because management is decentralized . . . the hospital will have a nine-member advisory board, eight of them from the local community."⁴ This is soft soap for a tough reality, and an issue of paramount concern. What HCA brought to Portsmouth, and what it would have brought to Boston, is money, plenty of it. The corporation plans to invest \$52 million in the Portsmouth facility. At McLean it agreed to spend \$35 million on a major construction project and an additional \$6.25 million to fund five Harvard professorships. The only attraction of HCA was ready access to capital, either through its own surplus or inexpensive loans. Burr describes the withering capital needs at MGH, currently estimated to be \$200 million, the increasing competition for philanthropic support, and third-party reimbursement policies, all of which prevent deriving an operating surplus to be used for capital develop-

ment. It also has been emphasized that access to low-cost, tax-exempt bonds is neither as easy or as inexpensive as it once was. Finally, new federal reimbursement policies no longer will recognize interest and depreciation expenses for most hospitals. While a federal policy on capital reimbursement is under development, there is mounting concern that many hospitals will have trouble managing capital costs and gaining access to capital markets.

Need for Capital a Paramount Issue

In a recent *New England Journal of Medicine* paper, Michael Bromberg, Executive Director of the Federation of American Hospitals, which represents proprietary hospitals, sees capital formation as the principal *raison d'être* for their existence. He states, "The final point is really the crux of the issue. What value are we to our communities? Quite simply, we are providing capital as well as services that have become absolutely necessary to more and more communities . . . it is estimated that by 1990 the unmet capital needs of the hospital industry will approach \$54 billion. Some 200,000 beds will have to be replaced, and 8,000 new ones built . . . if the investor is granted a fair return for his or her investment, the money will be there. If not, it won't."⁵

Can Rhode Island Resist?

Will our state face similar problems in capital formation, and will some of our institutions resort to the for-profit equity markets? Obviously, many of the same forces are creating pressures here as in other regions, but I really do not have a clear perception of how the future will unfold. The health department has produced some interesting data on capital values and projected spending. The book value of the land, buildings,

and equipment used by voluntary hospitals in 1982 was \$335 million. While this was the amount of money actually spent to build and purchase these assets, it would take approximately \$743 million to replace them today. A consultant from the US Department of Health and Human Services has estimated that Rhode Island hospitals could spend \$475 million in this decade. Between 1980 and 1983, some \$78.4 million were spent on capital expenditures in the state. We will get a further idea of how much and how fast to spend through the planning and certificate-of-need mechanisms.

As we proceed through this decade and into the next, I suspect that the primary concern will not be a capital cap, but will become the procurement of money to reach the total limitation, assuming that some cap becomes law. It should be clear from these remarks that I strongly favor a vigorous voluntary sector and would greatly regret the intrusion of the for-profit chains. We, like others, however, may come to need them for providing the necessary renovation of outdated plants and equipment and for accommodating new technology. If you feel as I do about the value of our trusteeships, a value which money literally cannot buy, we should begin to search for new and innovative ways of generating capital.

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SPECIAL REPORT

New Perspectives Concerning Do-Not-Resuscitate Orders

Thomas D. Gidley, LLB
Dennis A. Robbins, PhD, MPH

Technological advances which prolong life frequently present physicians with difficult medical, legal, and ethical decisions. Rhode Island has no statute, regulation, or judicial decision to guide those who are faced with such cases. The legal validity of decisions in these situations, as well as of hospital protocols dictating the process for such decisions is subject to question in Rhode Island. Judicial decisions in other states in the Quinlan,¹ Saikewicz,² Dinnerstein,³ Spring,⁴ and "Brother Fox"⁵ cases, all of which have received national attention, offer an interesting blend of discussions of irreversibility, prognosis, patient intent, substituted judgment, self-determination, and medical ethics. These cases, however, are not uniform in their approach to the problem. Moreover, because none is a Rhode Island situation, they offer no assistance to practitioners faced with deciding how to deal with a terminally-ill patient.

Two very recent court cases in New Jersey and California have raised issues which were not previously considered by the courts, further confusing the problem. These cases involve the question of removal of artificial feeding supports. The

New Jersey case, *In re Conroy*,⁶ decided by the Appellate Division of the New Jersey Superior Court in July 1983, involved Claire Conroy, an 84-year-old nursing home resident. She suffered from severe organic brain syndrome, but was not comatose or in a vegetative state. She did not meet the criteria for brain death. She was nourished by means of a nasogastric tube. In light of her hopeless prognosis, her guardian sought judicial permission to have the nasogastric tube removed to assure her death.

The trial judge, despite what he characterized as "misgivings," authorized removal of the nasogastric tube.⁷ The patient's guardian *ad litem* then appealed to the Appellate Division of the New Jersey Superior Court. The appellate court reversed the lower court decision, reasoning that, because Mrs. Conroy did not meet the criteria for brain death, was not comatose, and was not facing imminent death, the removal of feeding supports could not be sanctioned. The appellate court felt that withdrawal of nourishment constituted "active euthanasia."

The issues addressed by *Conroy* involve an act or mechanism which assures that death will occur when life supports are removed. Prior decisions had not dealt with removal of nourishment or with the question of whether continuation of nourishment constituted a totally medical decision as distinguished from a partially legal one.

The second recent case, adjudicated only three months after *Conroy*, was *Barber v Superior Court of the State of California*.⁸ The factual setting facing the physicians was similar to that in *Conroy*. Clarence Herbert, like Mrs. Conroy, was incompetent but did not meet the criteria for brain death. He also depended on artificial feeding supports. Un-

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like her, however, he was in a deeply comatose state. In *Barber*, two physicians, pursuant to a written request signed by Mr. Herbert's family stating that they wanted "all machines off that are sustaining life," caused his respirator and other life-sustaining equipment to be removed. He continued to breathe, but did not improve. Two days later the physicians, after consulting with the family, ordered the removal of the intravenous tubes providing hydration and nourishment. The patient died, and the physicians were charged with murder and conspiracy to murder. Although the New Jersey court had determined three months earlier that hastening death through the removal of feeding apparatus was "active euthanasia," the California Court of Appeal perceived such conduct as an "omission" rather than as an affirmative act. The California court indicated that physicians have no duty to continue treatment, even life-sustaining treatment, when they deem it to be useless, futile, or ineffective. The court terminated the prosecution.

The views taken by these two courts concerning the legality of removal of artificial feeding supports are irreconcilable. They generate substantial ambiguity as to the duty, if any, to continue treatment in essentially hopeless cases. These two cases underscore the urgent need to answer questions surrounding the legal propriety of do-not-

resuscitate (DNR) procedures in Rhode Island. Statewide procedures must be established to minimize uncertainty in this domain.

These types of situations often place the physician at odds with the patient. What lies in the best interests of the patient, or is in accordance with the patient's wishes, can often be clouded by the physician's concerns about potential civil or criminal liability, or both. These situations must be free of the agony and frustration spawned by legal uncertainty and fear of potential consequences. Firm guiding principles which are compatible and consistent with good medical practice must be devised.

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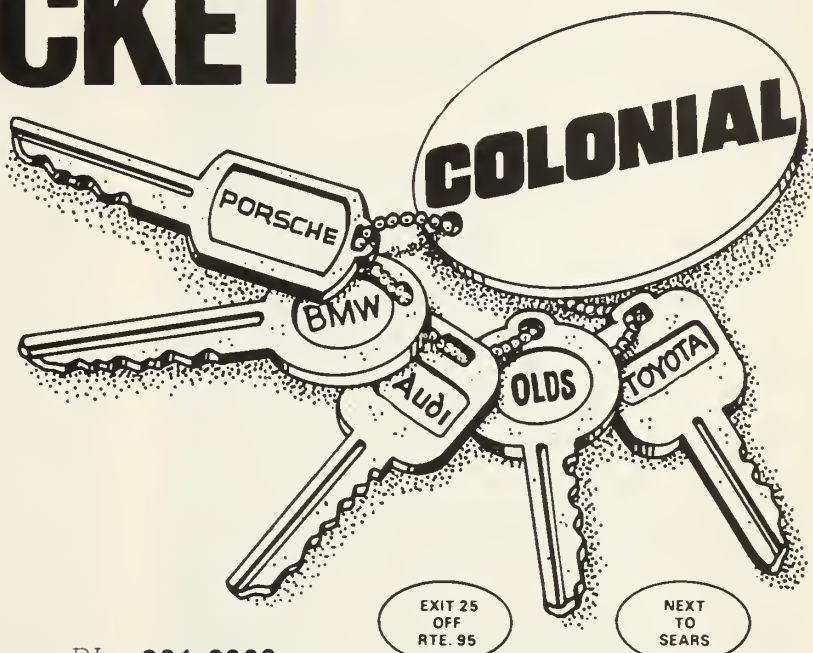
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HAVE YOU HEARD?

Regional domestic violence centers should be established to improve care for victims of rape, spouse abuse, child abuse, and other forms of domestic violence, according to an editorial in the August 1984 issue of *Annals of Emergency Medicine*. The editorial recommends that these centers be designed to train local health care providers to recognize and treat victims of domestic violence, to establish protocols which enable the legal system to deal more effectively with the assailant, to provide consultation to local health care providers, and to serve as referral sites for the evaluation and treatment of complex cases. A multidisciplinary approach, involving "representatives from emergency medicine, pediatrics, gynecology, geriatrics, social work, psychology, psychiatry, the legal profession, and child protective services," is necessary, the editorial advocates.

It has been estimated that 200,000 to 500,000 sexual assaults of female children occur each year. The incidence of spouse abuse and elder abuse also has shown a dramatic increase in recent years.

• • •

The increased popularity of cultured (yoghurt) and culture-containing (unfermented acidophilus milk) dairy foods within the past twenty years may be explained in part by their "healthy" image, according to the National Dairy Council. The nutritional and therapeutic value of these foods, however, varies considerably because of such factors as the type and strain of lactic starter organisms and differing fermentation and storage conditions. As a result, objective data are highly variable, often conflicting, and difficult to interpret. Moreover, the Council warns, because most of these studies have been *in vitro* or have involved experimental animals, their results frequently are not applicable to human beings.

In nutritional terms, the fermentation of milk results in the partial hydrolysis of protein, carbohydrate (lactose), and, to a lesser extent, fat. This is believed to result in a food with improved digestibility and possibly better growth rate and feed efficiency, at least in laboratory animals. When compared to milk, the concentration of most vitamins in fermented dairy foods is stable or decreased, while folic acid generally is increased. The mineral content of milk is un-

changed by fermentation, although the utilization of some minerals such as calcium may be improved.

It has been claimed that cultured dairy foods are beneficial for persons with lactose intolerance and other gastrointestinal disorders, to lower blood cholesterol levels, and to protect against colon cancer. There is some evidence that yoghurt, but not unfermented acidophilus milk, is well tolerated by lactose deficient persons. This has been attributed to the reduced lactose content of yoghurt and its bacterial lactose activity. The evidence is less clear, according to the Council, concerning the ability of fermented dairy foods to inhibit pathogenic and food spoilage organisms in the intestine which cause digestive problems. Similarly, additional studies are needed to substantiate the alleged hypocholesterolemic and anticarcinogenic effects of these products.

• • •

While as many as 40 per cent of American adults take vitamin supplements on a regular basis, some nutrition authorities have questioned whether their use is justified, since the food supply provides all essential nutrients. According to *Vitamin Issues*, a new publication of the Vitamin Nutrition Information Service, several groups of persons may be especially at risk for vitamin deficiencies. These include:

Women: Marginal consumption of vitamin A, vitamin B6, vitamin C, calcium, iron, and magnesium have been found among substantial numbers of American women.

Adolescents: According to a 1977-1978 survey conducted by the US Department of Agriculture, the diets of adolescent girls who consumed less than 70 per cent of their energy requirements met the recommended dietary allowance (RDA) for only one of the 12 nutrients studied. It has been suggested that micronutrient deficiencies may result from habitual dieting for weight control among female teenagers. While adolescent males generally averaged higher caloric intakes, several problem nutrients, especially iron, magnesium, and vitamin C, were identified among 20 to 40 per cent of the teenage boys studied.

Elderly: Problem nutrients found in recent studies include calcium, vitamin B6, thiamin, riboflavin, and niacin. Moreover, deficiencies in vitamin C were found in elderly men and in low-income groups.

Infants and children: With the exception of iron, vitamin C, and vitamin A, most infants and chil-

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Do You Know an Impaired Physician?

Treatment of physicians for alcohol addiction shows a favorable outcome in 83 per cent of cases, and treatment of physicians for drug addiction has a 95 per cent success rate. More than 70 per cent of the physicians entering treatment return to the active practice of medicine.

The Rhode Island Medical Society Committee on Impaired Physicians, chaired by Dr Herbert Rakatansky, meets monthly. It is a standing committee of the Society charged with "helping physicians whose professional judgments and capabilities are impaired by their difficulties with chemical dependency or other illnesses."

The Committee handles inquiries in *complete confidence*. If you know of a physician who needs an advocate and support in obtaining necessary treatment, please call or write Dr Rakatansky c/o The Committee on Impaired Physicians, Rhode Island Medical Society, 106 Francis Street, Providence 02903 (401/331-3207).

dren receive adequate amounts of micronutrients.

Low-income groups: While surveys conducted by the US Departments of Agriculture and Health and Human Services have shown that poor dietary patterns generally are more prevalent among the low-income groups, an analysis of food stamp households has revealed that deficiencies of vitamin C, thiamin, riboflavin, and iron present special problems.

Writing in the same monograph, Doctor Willard A. Krehl, Jefferson Medical College, contends that multivitamin supplements provide a "simple, economical, and highly practical way" for most persons to insure that they receive the essential micronutrients. According to Krehl, it is extremely difficult for many to obtain a sufficient supply of vitamins through their food supply because of such lifestyle factors as the sociological impact of working women, availability of convenience foods, and the prevalence of snacking. In 1982, an estimated 55 per cent of all children under the age of 18 years had mothers who worked outside the household. Moreover, the increase of single-parent households, especially those headed by women, has resulted in a "transformation of the American diet" with additional emphasis on convenience foods.

Doctor Alfred E. Harper, Professor of Biochemistry and Nutritional Sciences, University of Wisconsin at Madison, however, advocates the opposing viewpoint that vitamin supplements are unnecessary. He claims that the recommended daily allowances (RDA) may be too high for some persons. As a principal participant in the development for the RDAs, he says that they were intended for use only as guidelines and that "using the RDA as an inviolate standard is like setting the standard for height at 7 feet and assuming that all those under 7 feet have suffered growth retardation." Instead, Doctor Harper contends, the only way of ensuring lifelong nutritional health is through moderating lifestyle factors, such as diet and exercise.

• • •

Legislation has been proposed which would establish a National Center for Research Accountability for the purpose of conducting a full-text literature search prior to the funding of any grant proposal involving the use of live animals. Sponsored by Rep Robert G. Torricelli (D, NJ), the "Information Dissemination and Research Accountability Act" would require that all grant

proposals under consideration by any federal agency be forwarded to the new center for review. To be located at the National Library of Medicine, the center would employ 20 full-time experts in the biomedical information sciences with each expert to be a Presidential appointee. If the center determines that the grant proposal under review is essentially duplicative of other research already completed or in process, it would be empowered to void any funding of the project. According to the April 1984 issue of the *Bulletin* of the National Society for Medical Research, the bill's sponsor maintains that "thousands of animals are needlessly being subjected to redundant and duplicative laboratory experiments each year."



Estrogen replacement to prevent osteoporosis, a use of the hormone recently approved by the US Food and Drug Administration, is most effective when administered in dosages of 0.625 mg, according to a report in the June 1984 issue of *Obstetrics and Gynecology*. Women taking higher doses showed no additional benefits, while those taking less than 0.625 mg developed thinner bones, according to Doctors R. Lindsay, D. M. Hart, and D. M. Clark. Of 108 women who had undergone menopause or had their ovaries removed, the 30 who received the recommended dosage daily for two years did not show any bone loss. Women who received a daily dose of 1.25 mg did not appear to derive any additional benefits from the added estrogen. Those women who received a placebo or less than 0.625 mg, however, actually lost bone over the two years.

The estrogen supplements, the researchers found, also affected the amount of calcium retained by the women. Those patients in the 0.625 and 1.25 mg groups had high levels of calcium retention and low amounts of it in their urine. With a placebo or lower estrogen dose, the amount of calcium was low in the blood but high in the urine.



The most pressing health manpower problem in the United States is an oversupply of physician specialists, according to a recent report in *JAMA*. In a comparative study of the supply and distribution of physicians in Belgium, West Germany, the Netherlands, Great Britain, and the United States, Doctor Steven A. Schroeder, University of California Medical School at San Francisco, analyzed the numbers of physicians per

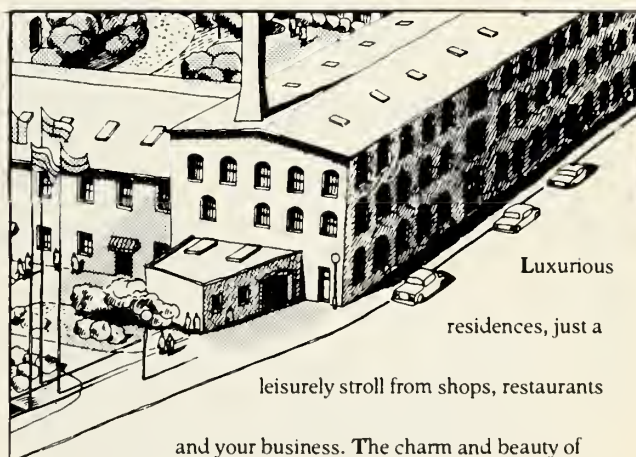


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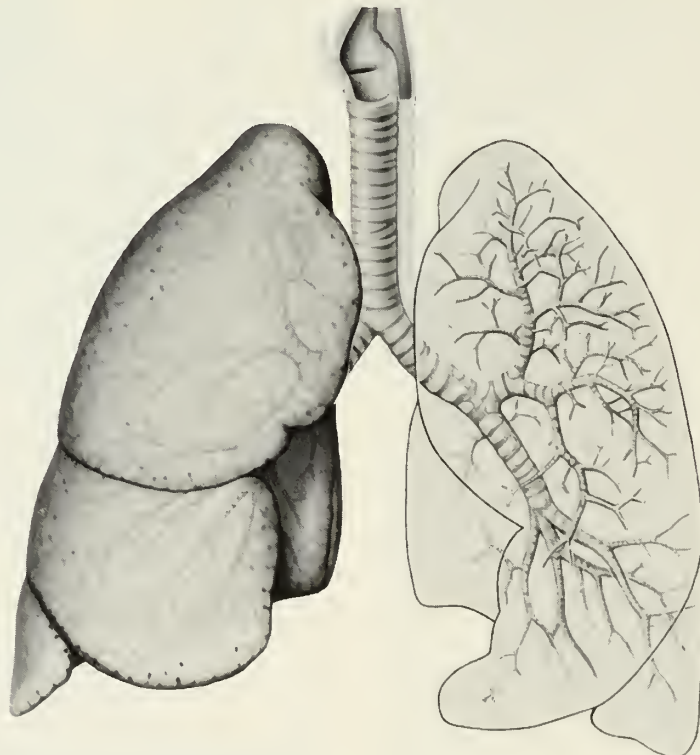
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Brief Summary Consult the package literature for prescribing information.

Indications and Usage Cecilor® (cefacor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae* (*Diplococcus pneumoniae*), *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci).

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Cecilor.

Contraindication Cecilor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings IN PENICILLIN SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS. AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Cecilor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, manage-

ment should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions *General Precautions* — If an allergic reaction to Cecilor® (cefacor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids. Prolonged use of Cecilor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Cecilor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended. As a result of administration of Cecilor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinistest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — *Pregnancy Category B* — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum

human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Cecilor® (cefacor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Cecilor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Cecilor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions Adverse effects considered related to therapy with Cecilor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100); pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Cecilor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have

occurred in patients with a history of penicillin allergy. Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematologic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note Cecilor® (cefacor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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10,000 population. The United States appears precisely in the middle of the five countries under consideration with 19.1 per 10,000.

Belgium currently has 24 physicians per 10,000 population, followed by West Germany, 22.9; the United States, 19.1; the Netherlands, 19.0; and the United Kingdom, 16.2. Moreover, the concentration of physicians in each country has increased substantially since 1960. Especially striking are the increases in Belgium and West Germany, which by 1980 had already reached two physicians per 1,000 persons and were projected to reach three per 1,000 by 1990.

Specialty distribution among the nations, however, was markedly higher for the US, with 84 per cent of all physicians designated as specialists, compared with only 24 per cent for Britain and 62 per cent for Holland. The numbers of physicians pose less a problem than their specialty distribution, Schroeder maintains. While the US does not appear to have a high concentration of physicians, it may be the "most vulnerable of the five countries to increases in medical care costs associated with physicians," he says, pointing out that Americans rely heavily on specialists for general medical care. In addition to a high concentration of surgical specialists, the US has high concentrations of psychiatrists, neurologists, radiologists, cardiologists, and gastroenterologists.

• • •

A drug now used to treat cardiac disease may also prevent cancer from metastasizing in laboratory animals, according to researchers at Wayne State University. A two-year study has shown that nefidipine inhibited formation of lung tumors by approximately 80 per cent in mice injected with tumor cells. The drug may represent a new approach for cancer therapy, according to Doctor John D. Taylor, Chairman of the University's Department of Biological Sciences. Discussions currently are underway concerning clinical testing of nefidipine.

• • •

Patients with aneurysms of the abdominal aorta appear to be at increased risk of developing cancer, according to a report in the July 1984 issue of the *Archives of Surgery*. Researchers from the Yale University School of Medicine report that 38 per cent of 69 patients with aortic aneurysms were found to have cancer five to ten years after surgical repair. However, only 13 per cent of a control group of 61 patients who had surgery for ather-

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osclerotic occlusive disease developed cancer within the same period.

The Yale researchers postulate that tissue copper levels may be involved with the development and metastasis of cancer. While animal studies have demonstrated a correlation between disturbances in copper metabolism and a propensity for the development of aneurysms, preliminary clinical analyses also have suggested a similar link in human beings. Copper has been implicated in the functioning of the immune system. Moreover, animal studies have revealed that reduced white-cell activity also is associated with aneurysms.

The Yale study also suggested that the mutation linked to the development of aneurysms might itself be carcinogenic. "If the relationship between aneurysmal disease and oncogenesis suggested by the present data can be confirmed in more comprehensive studies, it is possible that the association may reflect disturbed interactions between matrix proteins and epithelial cells of considerable biologic significance," the report concludes.

• • •

A synthetic lipid sphere containing the natural serum molecule C-reactive protein may prove useful in preventing the metastasis of cancer from the colon to the liver, according to a report recently published by the National Society for Medical Research. According to Doctor Sharad D. Deodhar, Cleveland Clinic Foundation, the encapsulated protein is engulfed by macrophage cells, which become activated against the tumor cells. Studies with laboratory mice in which colon cancer was induced revealed that the C-reactive protein inhibited the ability of the cancer to spread to the liver. Scientists, according to the same report, also have been studying the use of liposomes in controlling other metastases in experimental animals. These synthetic lipid spheres are hollow and can be used to deliver various drugs and natural biological products directly to the tumor site.

• • •

Regulatory agencies in both the United States and Britain recently reaffirmed their conclusions that aspartame may be consumed safely. The US Food and Drug Administration (FDA) has denied requests for a hearing on the safety issues related to aspartame. In a 59-page opinion published in the *Federal Register*, the agency noted that critics of the substance had not presented any unre-

solved safety questions in their petition for a public hearing. Moreover, the FDA said that the "hearing requests . . . either do not present sufficient credible evidence to warrant a hearing, or, where credible evidence is presented, even if true, it does not raise a material question of fact." The objections to aspartame primarily concerned the potential adverse effects of methyl alcohol, as well as other breakdown products of aspartame, and the alleged behavioral reactions and other side effects of aspartame consumption.

In the United Kingdom, regulations allowing the use of aspartame in food and beverages became effective in September 1983. Approval of the regulations came after an extensive review of the research on aspartame by a committee of independent experts which advises the British government on potential health hazards.



Many sun worshippers refuse to use sunscreens even when they are informed of the hazards of solar exposure and of the benefits provided by sunscreens, according to a new study reported in the June 1984 *Archives of Dermatology*. Researchers from the Pennsylvania State University College of Medicine in Hershey surveyed 489 patients during the summer months. While 71 per cent of the respondents reported sunbathing at least one hour per week, only 41 per cent used sunscreens, typically in the belief that they would promote tanning. The subjects were given samples of appropriate sunscreens and informational pamphlets. Some 340 patients were telephoned four weeks later for follow-up evaluation. Although virtually all demonstrated better knowledge of the risks of excessive exposure, none of them had used the sunscreens. The researchers note the difficulty of changing behavior because of the widespread societal belief that a tan is healthier.



Children are more likely to have headaches that occur on weekdays and are briefer than headaches affecting adults, according to a report in the July 1984 issue of *Archives of Neurology*. Researchers from the Harvard Medical School developed a computerized headache interview program that was completed by 255 children, adolescents, and adults. It was found that the frequency of headaches did not vary with age, and seasonal variations were not prominent in any age group. ■

Information for Authors

Manuscripts: Manuscripts will be accepted for consideration with the understanding that they are original contributions, have never been published or submitted elsewhere, and are submitted only to the *Rhode Island Medical Journal*.

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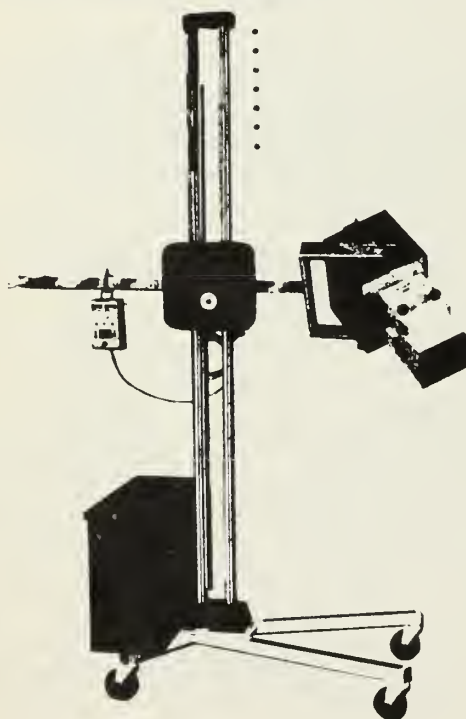
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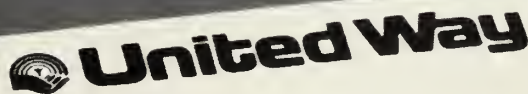
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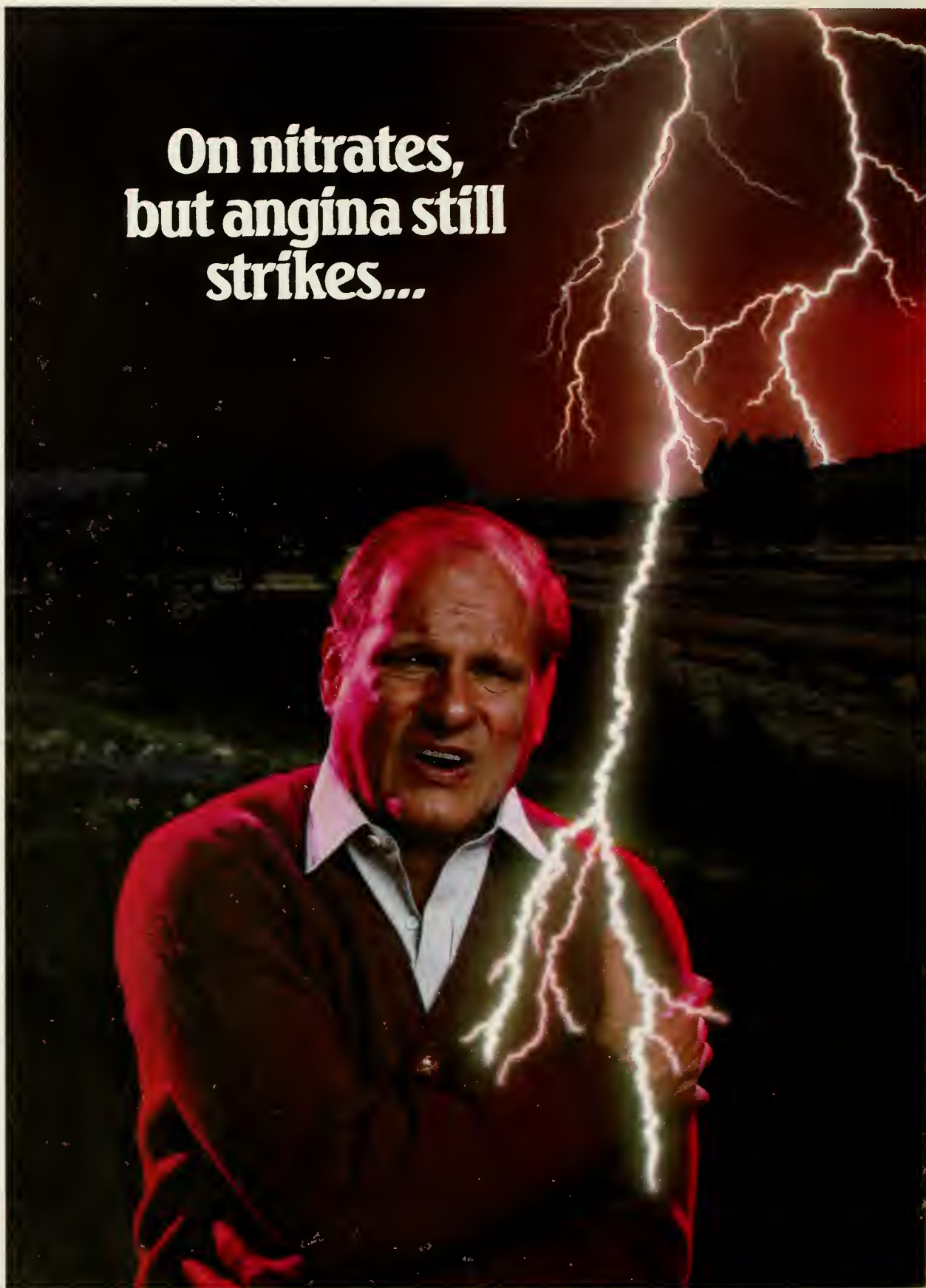
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Precautions: ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of overdosage. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, patients should be monitored closely. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function or in patients who have also recently received methyl dopa. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patient carefully monitored. ISOPTIN may have an additive hypotensive effect in patients receiving blood-pressure-lowering agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. **Pregnancy Category C:** There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor, and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use.

Adverse Reactions: Hypotension (2.9%), peripheral edema (1.7%), AV block, 3rd degree (0.8%), bradycardia: HR<50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%). The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: confusion, paresthesia, insomnia, somnolence, equilibrium disorders, blurred vision, syncope, muscle cramps, shakiness, claudication, hair loss, maculae, and spotty menstruation. Overall continuation rate of 94.5% in 1,166 patients.

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Chronic studies in rats and monkeys have shown mild renal toxicity with papillary edema and necrosis. Renal papillary necrosis has rarely been shown in humans treated with Motrin Tablets.

Precautions: Blurred and/or diminished vision, scotomata, and/or changes in color vision have been reported. If these develop, discontinue Motrin Tablets and the patient should have an ophthalmologic examination, including central visual fields and color vision testing.

Fluid retention and edema have been associated with Motrin Tablets; use with caution in patients with a history of cardiac decompensation or hypertension. In patients with renal impairment, reduced dosage may be necessary. Prospective studies of Motrin Tablets safety in patients with chronic renal failure have not been done.

Motrin Tablets can inhibit platelet aggregation and prolong bleeding time. Use with caution in persons with intrinsic coagulation defects and on anticoagulant therapy.

Patients should report signs or symptoms of gastrointestinal ulceration or bleeding, skin rash, weight gain, or edema.

Patients on prolonged corticosteroid therapy should have therapy tapered slowly when Motrin Tablets are added.

The antipyretic, anti-inflammatory activity of Motrin Tablets may mask inflammation and fever.

As with other nonsteroidal anti-inflammatory drugs, borderline elevations of liver tests may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy. Meaningful elevations of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with ibuprofen as with other nonsteroidal anti-inflammatory drugs. If liver disease develops or if systemic manifestations occur (e.g. eosinophilia, rash, etc.), Motrin should be discontinued.

Drug interactions: Aspirin: used concomitantly may decrease Motrin blood levels.

Coumarin: bleeding has been reported in patients taking Motrin and coumarin.

Pregnancy and nursing mothers: Motrin should not be taken during pregnancy or by nursing mothers.

Adverse Reactions: The most frequent type of adverse reaction occurring with Motrin is gastrointestinal of which one or more occurred in 4% to 16% of the patients.

Incidence Greater than 1% (but less than 3%)—Probable Causal Relationship

Gastrointestinal: Nausea,* epigastric pain,* heartburn,* diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence); **Central Nervous System:** Dizziness,* headache, nervousness; **Dermatologic:** Rash* (including maculopapular type), pruritus; **Special Senses:** Tinnitus; **Metabolic/Endocrine:** Decreased appetite; **Cardiovascular:** Edema; fluid retention (generally responds promptly to drug discontinuation; see PRECAUTIONS).

Incidence less than 1%—Probable Causal Relationship**

Gastrointestinal: Gastric or duodenal ulcer with bleeding and/or perforation, gastrointestinal hemorrhage, melena, gastritis, hepatitis, jaundice, abnormal liver function tests; **Central Nervous System:** Depression, insomnia, confusion, emotional lability, somnolence, aseptic meningitis with fever and coma; **Dermatologic:** Vesiculobullous eruptions, urticaria, erythema multiforme, Stevens-Johnson syndrome, alopecia; **Special Senses:** Hearing loss, amblyopia (blurred and/or diminished vision, scotomata, and/or changes in color vision) (see PRECAUTIONS); **Hematologic:** Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia (sometimes Coombs positive); thrombocytopenia with or without purpura, eosinophilia, decreases in hemoglobin and hematocrit; **Cardiovascular:** Congestive heart failure in patients with marginal cardiac function, elevated blood pressure, palpitations; **Allergic:** Syndrome of abdominal pain, fever, chills, nausea and vomiting, anaphylaxis; bronchospasm (see CONTRAINDICATIONS); **Renal:** Acute renal failure in patients with pre-existing significantly impaired renal function, decreased creatinine clearance, polyuria, azotemia, cystitis, hematuria; **Miscellaneous:** Dry eyes and mouth, gingival ulcer, rhinitis.

Incidence less than 1%—Causal Relationship Unknown**

Gastrointestinal: Pancreatitis; **Central Nervous System:** Paresthesias, hallucinations, dream abnormalities, pseudotumor cerebri; **Dermatologic:** Toxic epidermal necrolysis, photoallergic skin reactions; **Special Senses:** Conjunctivitis, diplopia, optic neuritis; **Hematologic:** Bleeding episodes (e.g., epistaxis, menorrhagia); **Metabolic/Endocrine:** Gynecomastia, hypoglycemic reaction; **Cardiovascular:** Arrhythmias (sinus tachycardia, sinus bradycardia); **Allergic:** Serum sickness, lupus erythematosus syndrome, Henoch-Schönlein vasculitis; **Renal:** Renal papillary necrosis.

*Reactions occurring in 3% to 9% of patients treated with Motrin. (Those reactions occurring in less than 3% of the patients are unmarked.)

**Reactions are classified under "Probable Causal Relationship (PCR)" if there has been one positive rechallenge or if three or more cases occur which might be causally related. Reactions are classified under "Causal Relationship Unknown" if seven or more events have been reported but the criteria for PCR have not been met.

Overdosage: In cases of acute overdosage, the stomach should be emptied. The drug is acidic and excreted in the urine so alkaline diuresis may be beneficial.

Dosage and Administration: Rheumatoid arthritis and osteoarthritis. Suggested dosage is 300, 400, or 600 mg t.i.d. or q.i.d. Do not exceed 2400 mg per day. Mild to moderate pain: 400 mg every 4 to 6 hours as necessary.

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Caution patients about driving, operating hazardous machinery or drinking alcohol during therapy. Limit dose to 15 mg in elderly or debilitated patients. Contraindicated during pregnancy

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References: 1. Kales J et al: *Clin Pharmacol Ther* 12:691-697, Jul-Aug 1971. 2. Kales A et al: *Clin Pharmacol Ther* 18:356-363, Sep 1975. 3. Kales A et al: *Clin Pharmacol Ther* 19:576-583, May 1976. 4. Kales A et al: *Clin Pharmacol Ther* 32:781-788, Dec 1982. 5. Frost JD Jr, DeLucchi MR: *J Am Geriatr Soc* 27:541-546, Dec 1979. 6. Kales A, Kales JD: *J Clin Pharmacol* 3:140-150, Apr 1983. 7. Greenblatt DJ, Allen MD, Shader RI: *Clin Pharmacol Ther* 21:355-361, Mar 1977. 8. Zimmerman AM: *Curr Ther Res* 13:18-22, Jan 1971. 9. Amrein R et al: *Drugs Exp Clin Res* 9(1):85-99, 1983. 10. Monti JM: *Methods Find Exp Clin Pharmacol* 3:303-326, May 1981. 11. Greenblatt DJ et al: *Sleep* 5(Suppl 1):S18-S27, 1982. 12. Kales A et al: *Pharmacology* 26:121-137, 1983.

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Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, light-headedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase, and paradoxical reactions, e.g., excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. **Adults:** 30 mg usual dosage, 15 mg may suffice in some patients. **Elderly or debilitated patients:** 15 mg recommended initially until response is determined.

Supplied: Capsules containing 15 mg or 30 mg flurazepam HCl.



Roche Products Inc.
Manati, Puerto Rico 00701

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